

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON)
TALCUM POWDER PRODUCTS)
MARKETING, SALES PRACTICES AND) MDL Docket No. 2738
PRODUCTS LIABILITY LITIGATION)

This Document Relates To All Cases)

**DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON
CONSUMER INC.'S MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO EXCLUDE PLAINTIFFS' EXPERTS'
ASBESTOS-RELATED OPINIONS**

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INTRODUCTION

Legions of government agencies, independent testing labs and major universities have tested Johnson's Baby Powder® and Shower-to-Shower® (the "Products") – including the U.S. Food & Drug Administration ("FDA"), National Institute for Occupational Safety & Health ("NIOSH") and the Harvard School of Public Health – without finding asbestos. In order to overcome this consensus, plaintiffs turned to litigation specialists Dr. William Longo and his assistant Dr. Mark Rigler. The reason: By his own admission, Dr. Longo will *call something asbestos even when it's not*.

One court has described Dr. Longo's work as "junk science" – concluding that studying "Dr. Longo's testimony reveal[ed] it to be practiced and to employ misdirection and evasiveness. It is at best disingenuous, not credible and unsupported by any respectable community of scientists."¹

The same is true here. Drs. Longo and Rigler's opinions, as well as the opinions of plaintiffs' other experts who opine on the supposed asbestos content of the Products, are based on non-methodological, results-oriented, litigation-driven analyses that do not come close to satisfying *Daubert*, for several reasons.

¹ Order Ex. A at 1, *In re Lamar Cty. Asbestos Litig.*, No. 2000-3559 (Tex. Dist. Ct. July 5, 2001) ("*In re Lamar Cty. Order*") (attached as Ex. E15 to Omnibus Certification of Julie Tersigni, Esq. ("Tersigni Cert.")).

First, Drs. Longo and Rigler have not reliably shown that the Products contain asbestos. They redefine “asbestos” in order to match what they claim to have found in the Products. Dr. Longo acknowledges that the “structure [that] comes from breaking apart non-asbestos” minerals does “not magically become, in fact, asbestos.”² But he admits he will nevertheless “count it and report it in [his] reports as asbestos,” *even though it is not*.³

Beyond changing the definition of asbestos for litigation ends, the analysts employed by Drs. Longo and Rigler use their microscopes for theater, not for science. (Drs. Longo and Rigler did not run their own analyses.) Published and accepted protocols require the generation of quantitative data for the four microscopy techniques that they purport to use so that there can be a comparison to published and agreed-upon standards. Drs. Longo and Rigler, however, did not disclose those data or simply refused to generate them. They do this, quite deliberately, to prevent third-party verification of their results. Instead, they “eyeball” graphical results and purport to compare those to MAS internal references that (if they even exist) the Plaintiffs’ Steering Committee (“PSC”) did not produce. Worse, they use their microscopes in ways contrary to the published

² (Tr. 149:14-17, *Rimondi v. BASF Catalysts LLC*, No. MID-L-2912-17 (N.J. Super. Ct. Law Div. Mar. 5, 2019) (“Longo *Rimondi* Tr. Vol. I”) (attached as Ex. E29 to Tersigni Cert.)) Drs. Longo and Rigler have issued the same report they did here in numerous other cases, including *Rimondi*.

³ (*Id.* 149:18-20.)

methodologies, often in ways that they themselves admit cannot uniquely identify the minerals that they say they have identified.

Second, many of plaintiffs’ experts, operating well beyond the limits of their expertise, attempt to piggyback on Drs. Longo and Rigler’s findings to opine that perineal talc use causes ovarian cancer because it contains asbestos. The studies they rely on ***at most*** suggest a weak link between ovarian cancer and heavy occupational exposure to crocidolite asbestos (the most potent form of asbestos). But even Drs. Longo and Rigler only claim to find the most minute levels of less potent forms of asbestos in the Products: ranging down to ***3.3 millionths of a percent***. There is only one expert in the litigation, Dr. Nadia Moore, who analyzed exposure. She concluded that cumulative lifetime exposure to the levels of asbestos plaintiffs claim are present in the Products is ***at least 4,000 times below*** the lifetime asbestos concentration associated with the Occupational Safety and Health Administration’s (“OSHA”) permissible exposure limit; and ***at least 29,000 times below*** the level of tremolite asbestos considered protective of mesothelioma.

Third, plaintiffs seek to buttress Drs. Longo and Rigler’s report with the opinions of Drs. Mark Krekeler and Robert Cook, two geologists who assert that cherry-picked documents provided to them by plaintiffs’ counsel establish that talc deposits used to source the Products were contaminated with asbestos. But these opinions are inherently unreliable. For one thing, the experts’ “research” was

limited to a review of documents hand-picked by plaintiffs' counsel and pre-analyzed for them in charts. This is not a scientific methodology. In addition, the experts' opinions are not supported by the data on which they are based. Instead, these materials relate largely to: the mineralogy of geographical regions other than those in which talc for the Products was mined; testing performed on non-talc ore; testing performed on talc *not* used to source the Products (i.e., industrial talc and talc from other regions); test results that do not identify asbestiform minerals; and test results that were later disavowed or rescinded. Thus, they cannot support plaintiffs' experts' opinions about asbestos contamination of the Products.

For all of these reasons, the Court should exclude plaintiffs' experts' opinions regarding the supposed presence of asbestos in the Products and its potential to cause ovarian cancer.

BACKGROUND

A. What Is Asbestos?

“Asbestos” is a collective term describing a group of six minerals that, under certain rare geological conditions, can form in bundles composed of long, thin, extremely flexible fibers.⁴ When they form in this unique way, they are “asbestiform.”⁵ When they do not, they are “nonasbestiform.”⁶

The way a mineral forms in nature is known as its “habit.”⁷ Thus, “asbestiform” is an adjective that describes the distinctive growth pattern – or habit

⁴ E.g., Perkins & Harvey, U.S. Env’tl Protection Agency, *Test Method: Method for the Determination of Asbestos in Bulk Building Materials A-1* (1993) (“EPA R-93”) (attached as Ex. A112 to Tersigni Cert.); Int’l Org. for Standardization, *Ambient Air – Determination of asbestos fibres – Direct-transfer transmission electron microscopy method 2* (1995) (attached as Ex. A76 to Tersigni Cert.); Int’l Agency for Research on Cancer, World Health Org., 93 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc 277* (2010) (“IARC 2010 Monograph”) (attached as Ex. A72 to Tersigni Cert.); Nat’l Inst. for Occupational Health and Safety, *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research 7-8* (2011) (“NIOSH Roadmap”) (attached as Ex. A98 to Tersigni Cert.); 30 C.F.R. § 56.5001(b)(1).

⁵ IARC 2010 Monograph at 277; Int’l Org. for Standardization, *Air Quality – Bulk Materials: Part 1: Sampling and qualitative determination of asbestos in commercial bulk materials 2* (2012) (“ISO 22262-1”) (attached as Ex. A74 to Tersigni Cert.).

⁶ IARC 2010 Monograph at 277.

⁷ ISO 22262-1 at 5.

– of asbestos minerals.⁸ Minerals that crystallize in an asbestiform habit have a crystal structure that can be separated into fibers with high tensile strength and flexibility.⁹

Each of the six minerals comes in a nonasbestiform, and (much more rarely) an asbestiform version:¹⁰

Mineral Family	Non-Asbestiform	Asbestiform
Serpentine	Antigorite/Lizardite	Chrysotile
Amphibole	Riebeckite	Crocidolite
Amphibole	Grunerite-Cummingtonite	Amosite
Amphibole	Tremolite	Tremolite Asbestos
Amphibole	Anthophyllite	Anthophyllite Asbestos
Amphibole	Actinolite	Actinolite Asbestos

The World Health Organization’s International Agency for Research on Cancer (“IARC”) – one of the authorities plaintiffs’ medical experts primarily rely on for their causation opinions – explained: “[W]hen asbestiform, they constitute asbestos

⁸ IARC 2010 Monograph at 277. (*See also* Expert Report of M. Darby Dyar, Ph.D. (“Dyar Rep.”) at 10, Feb. 25, 2019 (attached as Ex. C30 to Tersigni Cert.).)

⁹ ISO 22262-1 at 2; IARC 2010 Monograph at 277; EPA R-93 at A-1; NIOSH Roadmap at 7, 9. (Dyar Rep. at 10.)

¹⁰ Int’l Agency for Research on Cancer, World Health Org., 100 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and Dusts* 220 (2012) (“IARC 2012 Monograph”) (attached as Ex. A70 to Tersigni Cert.); *see also* IARC 2010 Monograph at 277, 411-13 (“[T]hese six minerals occur more commonly in a nonasbestiform habit.”). Five of these minerals belong to the amphibole mineral family; chrysotile, by contrast, belongs to the serpentine mineral family. While both groups are sheet silicates, they have distinct chemical formulas. *See* ISO 22262-1 at 2, 7. For example, amphiboles generally contain iron; serpentine minerals do not. *Id.*

and, when not asbestiform, they are referred to as mineral fragments or cleavage fragments.”¹¹

As the above chart demonstrates, asbestiform and nonasbestiform varieties of the same mineral sometimes have similar names, and sometimes entirely different names. For example, “riebeckite is the non-asbestos version of crocidolite.”¹² By contrast, there “are asbestos types of tremolite, there are non-asbestos types of tremolite.”¹³ Accordingly, as Dr. Longo acknowledges, the “word tremolite does not automatically mean asbestos.”¹⁴ The two are typically distinguished by referring to the nonasbestiform variety as simply “tremolite,” while referring to the asbestiform variety as “asbestiform tremolite” or “tremolite asbestos.”

Because they formed differently in nature, asbestiform and nonasbestiform minerals have different properties. For example, asbestiform minerals “possess

¹¹ IARC 2010 Monograph at 277. (*See also* Dep. of Robert Cook, Ph.D. (“Cook Dep.”) 108:14-20, Jan. 30, 2019 (attached as Ex. B43 to Tersigni Cert.) (it is the “asbestiform version of those amphiboles that is defined as, quote, asbestos”).)

¹² (Longo *Rimondi* Tr. Vol. I 141:23-25.)

¹³ (*Id.* 142:24-143:1; Dep. of Mark W. Rigler, Ph.D. (“Rigler Dep.”) 201:2-4, Feb. 6, 2019 (attached as Ex. B35 to Tersigni Cert.).)

¹⁴ (Longo *Rimondi* Tr. Vol. I 142:11-13.)

high tensile strength and flexibility.”¹⁵ In this way, the difference between an asbestiform and nonasbestiform mineral is like the difference between diamond and graphite. Both are made of the same element (carbon). Both can be ground or cleaved to the same size or shape. But you can’t cut glass with graphite.

And though they have the same chemical composition, the two look very different because of the different geological conditions in which they were formed.¹⁶



Non-Asbestiform Tremolite



Asbestiform Tremolite

Figure 1: Nonasbestiform and asbestiform varieties of the same minerals

Every federal regulation or statute defines asbestos in a similar way. For example, the regulations promulgated by OSHA define “asbestos” as only the asbestiform varieties of the six regulated minerals. 29 C.F.R. § 1910.1001(b). The

¹⁵ (2d Suppl. Expert Report of William E. Longo, Ph.D. & Mark W. Rigler, Ph.D. (“2d Suppl. Longo Rep.”) at 24, Feb. 1, 2019 (attached as Ex. C1 to Tersigni Cert.).)

¹⁶ Campbell et al., Bureau of Mines, *Selected Silicate Minerals and Their Asbestiform Varieties* 7 (1977) (“Campbell 1977”) (attached as Ex. A18 to Tersigni Cert.).

federal regulations promulgated by the Environmental Protection Agency (“EPA”) similarly define “asbestos” as “the *asbestiform varieties*” of those minerals. 40 C.F.R. § 763.163; 40 C.F.R. § 61.141 (same).¹⁷ The U.S. Mine Safety and Health Administration (“MSHA”), which regulates talc mines and mills, defines asbestos in the same way, 30 C.F.R. § 56.5001(b), and has expressly stated that its definition of asbestos “does not include nonfibrous or nonasbestiform minerals,” *see* 73 Fed. Reg. 11284, 11292 (2008).

Congress, too, has embraced this fundamental distinction between asbestos and nonasbestiform minerals. For example, the Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq.*, authorizes federal regulation of toxic substances that pose health hazards. It limits the definition of asbestos to “asbestiform varieties” of the six minerals. 15 U.S.C. § 2642(3).

Accordingly, in order to determine whether particles are asbestos, one must conclude that (1) they are one of the six relevant minerals, and (2) they are the asbestiform version of that mineral. As one of the protocols Drs. Longo and Rigler purport to rely on explains: “Since the non-asbestiform analogues of the

¹⁷ *See also Hanson v. Colgate-Palmolive Co.*, 353 F. Supp. 3d 1273, 1278 (S.D. Ga. 2018) (relying on the OSHA and EPA definition).

amphiboles are not generally regulated, it is also *necessary to discriminate between the asbestiform and nonasbestiform analogues* of these minerals.”¹⁸

B. Cleavage Fragments Are Not Asbestos.

MSHA explains that “when pressure is applied, the nonasbestiform crystals fracture into prismatic particles, which are called cleavage fragments because they result from the particle’s breaking or cleavage. Cleavage fragments may be formed when nonfibrous minerals are crushed, as may occur in mining and milling operations.” 73 Fed. Reg. 11284 (2008).

Nonasbestiform amphibole is like ordinary rock, no matter what one does with it. As Dr. Longo explained, “You can’t take pieces of the non-asbestos rock and break it up and then call it asbestos.”¹⁹ Regardless of size, nonasbestiform particles simply have not crystallized in the specific way that leads to the unique properties that make them asbestos, and that make asbestos dangerous.

Based on over 25 years of study, the medical and regulatory communities have embraced the distinction between asbestiform and nonasbestiform minerals. In 1992, OSHA undertook a comprehensive study of scientific data and opinions to

¹⁸ Int’l Org. for Standardization, *Air Quality – Bulk Materials: Part 2: Quantitative determination of asbestos by gravimetric and microscopical methods* 13 (2014) (“ISO 22262-2”) (attached as Ex. A75 to Tersigni Cert.) (emphasis added).

¹⁹ (Longo *Rimondi* Tr. Vol. I 147:23-148:1.)

determine whether nonasbestiform minerals should be regulated as asbestos.²⁰ The agency reviewed decades of testing and literature and determined that “substantial evidence is lacking to conclude that non-asbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health effect as asbestos.”²¹ Specifically, the agency found no credible link between exposure to nonasbestiform minerals and cancer.²²

The United States Geological Survey (“USGS”) states that “when it comes to health risk,” it “matter[s] whether an amphibole is asbestiform,” and that “available evidence supports a conclusion that exposure to nonasbestiform cleavage fragments is not likely to produce a significant risk of developing asbestos-related disease.”²³ NIOSH – OSHA’s scientific and research arm – has similarly declared that “nonasbestiform minerals are not ‘asbestos’ or ‘asbestos minerals,’” and only “exposure to fibers from the asbestos minerals” is credibly linked to adverse health effects in epidemiological studies.²⁴

²⁰ 57 Fed. Reg. 24310 (1992).

²¹ *Id.*

²² *Id.* at 24311.

²³ U.S. Geological Survey, *Some Facts About Asbestos 2* (2001) (attached as Ex. A146 to Tersigni Cert.) (quoting 57 Fed. Reg. 24310).

²⁴ NIOSH Roadmap at vii, 3.

Also, perhaps most importantly for these proceedings, none of plaintiffs' *medical* experts has presented any evidence that cleavage fragments cause ovarian cancer. When asked whether he factored into his opinions "the difference between asbestiform and non-asbestiform minerals," plaintiffs' gynecological oncologist Dr. Clarke-Pearson only stated "[w]ell, I'm quite certain, based on IARC, that asbestiform minerals are carcinogenic."²⁵ Despite the questioner prompting him to do so, he did not state whether in his opinion nonasbestiform minerals were carcinogenic as well.²⁶ In fact, neither Dr. Clarke-Pearson nor Dr. Singh, one of plaintiffs' epidemiologists, even knew what cleavage fragments were when asked at their depositions.²⁷ It is for these reasons that plaintiffs' experts need to stretch their made-for-litigation definition of asbestos.

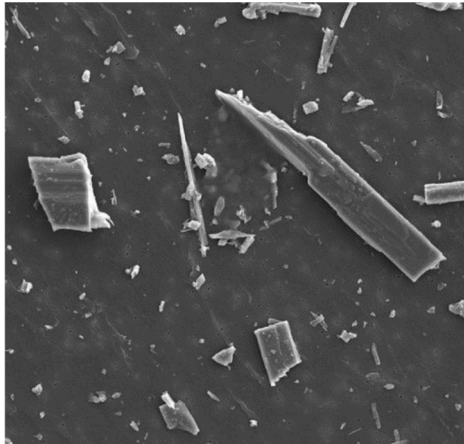
²⁵ (Dep. of Daniel L. Clarke-Pearson, M.D. ("Clarke-Pearson Dep.") 287:7-17, Feb. 4, 2019 (attached as Ex. B10 to Tersigni Cert.).)

²⁶ (*See id.* 287:19-20.)

²⁷ (*See id.* 286:10-12; Dep. of Sonal Singh, M.D., M.P.H. 298:9-12, Jan. 16, 2019 (attached as Ex. B47 to Tersigni Cert.).)

C. Asbestiform And Nonasbestiform Particles Have Distinct Characteristics.

The size and shape of a particle is known as its “morphology.”²⁸ Here are images provided by the USGS taken using a “scanning electron microscope” (“SEM”) (a kind of microscope Drs. Longo and Rigler did not use here):²⁹



Tremolite Cleavage Fragments



Tremolite Asbestos

Figure 2: SEM images of nonasbestiform tremolite cleavage fragments and tremolite asbestos

Asbestos fibers tend to be longer and thinner, and nonasbestiform particles tend to be wider and chunkier.³⁰ But that is not to say that *every* asbestos fiber is longer than *every* cleavage fragment, or that *every* asbestos fiber has a greater

²⁸ EPA R-93 at A-4.

²⁹ Tremolite Images Nos. 18, 20, U.S. Geological Survey (attached as Ex. A147 to Tersigni Cert.).

³⁰ NIOSH Roadmap at 6, 42. (See also Dyar Rep. at 52-54.)

“aspect ratio” than *every* cleavage fragment.³¹ When nonasbestiform minerals break up, they “break in all sorts of different shapes and sizes” and some pieces “may be long and thin.”³² And the “long, thin cleavage fragments can resemble asbestos fibers.”³³

D. Drs. Longo And Rigler: Who Are They And What Are Their Opinions?

Dr. Longo is the President and a 75% owner of his lab Material Analytical Services, LLC (“MAS”).³⁴ Dr. Rigler, a microbiologist, is MAS’s Chief Science Officer.³⁵ 95% of the time that he is in court, Dr. Longo is testifying for plaintiffs’ attorneys in asbestos litigation.³⁶

Dr. Longo self-reports that MAS has billed over \$30 million for legal work on behalf of plaintiffs in the last 30 years.³⁷ In fact, as Dr. Longo recently

³¹ An aspect ratio is the proportions of an object’s length to width. *See* ISO 22262-1 at 3 (defining aspect ratio). An object with a 3:1 (“three-to-one”) aspect ratio is three times longer than it is wide.

³² (Longo *Rimondi* Tr. Vol. I 148:3-6.)

³³ (*Id.* 148:8-10.)

³⁴ (Curriculum Vitae of Dr. William E. Longo, Ph.D. (attached as Ex. C4 to Tersigni Cert.); Tr. 174:7-11, *Leavitt v. Johnson & Johnson*, No. RG17882401 (Cal. Super. Ct. Feb. 7, 2019) (“Longo 2/7/19 *Leavitt* Tr.”) (attached as Ex. E25 to Tersigni Cert.).)

³⁵ (Curriculum Vitae of Dr. Mark W. Rigler, Ph.D. (attached as Ex. C3 to Tersigni Cert.).)

³⁶ (Longo 2/7/19 *Leavitt* Tr. 178:20-23.)

³⁷ (*Id.* 174:22-175:2.)

explained, working for plaintiffs in litigation “has allowed our lab to survive.”³⁸

He believes *every* plaintiffs’ attorney in the country discloses him in all of their asbestos lawsuits.³⁹ During this time, Dr. Longo has given somewhere between 2,500 and 3,000 depositions.⁴⁰ In just the last five years, Dr. Longo has testified at least once a week, every week.⁴¹ 100% of his work to date in talc litigation has been for plaintiffs.⁴²

Courts have excluded Dr. Longo’s opinions on numerous occasions.⁴³ In some instances they have called his work “junk science” and “pseudo-science at best.”⁴⁴

³⁸ (Tr. 1653:19-22, *Olson v. Brenntag N. Am.*, No. 190328 (N.Y. Sup. Ct. Feb. 26, 2019) (“Longo *Olson* Tr.”) (attached as Ex. E28 to Tersigni Cert.).)

³⁹ (Longo 2/7/19 *Leavitt* Tr. 179:3-7.)

⁴⁰ (Tr. 171:20-22, *Brick v. Brenntag N. Am., Inc.*, No. BC674595 (Cal. Super. Ct. May 31, 2018) (attached as Ex. E23 to Tersigni Cert.).)

⁴¹ (Tr. 3519:10-13, *Allen v. Brenntag N. Am.*, No. DR180132 (Cal. Super. Ct. Oct. 19, 2018) (attached as Ex. E22 to Tersigni Cert.).)

⁴² (Longo *Olson* Tr. 1646:24-1647:2.)

⁴³ See, e.g., Rulings on Mots. in Lim., Ex. B at 27-41, *Weirick v. Brenntag N. Am., Inc.*, No. BC656425 (Cal. Super. Ct. Jul. 23, 2018) (attached as Ex. E16 to Tersigni Cert.); Tr. of Proceedings 886:18-893:25, *Allen v. Brenntag N. Am., Inc.*, No. DR 180132 (Cal. Super. Ct. Oct. 1, 2018) (attached as Ex. E18 to Tersigni Cert.); *In re Lamar Cty.* Order (calling Longo’s MAS tests “junk science”); *Krik v. Crane Co.*, 71 F. Supp. 3d 784, 790 (N.D. Ill. 2014); *Suoja v. Owens-Ill., Inc.*, No. 05-CV-219-BBC, 2015 WL 2341436, at *3 (W.D. Wis. May 14, 2015); *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, 2010 WL 7699456, at *76 (N.D. Ohio June 4, 2010); *In re Garlock Sealing Techs., LLC*, 504 B.R. 71 (Bankr. W.D.N.C. 2014) (finding Dr. Longo’s studies “pseudo-science at best”); *Dugas v.*

Dr. Longo has *said* (under oath) that he has tested cosmetic talc only for purposes of litigation, and only began doing so in 2017 after being contacted by plaintiffs' attorneys.⁴⁵ But back in 2002 before he was hired for this litigation he testified: "[W]e have done our own studies on talc, but what I haven't been able to do is find a cosmetic where I can say, yes, that has asbestos in it."⁴⁶ He said then that he was "very familiar" with the issue and that cosmetic talc containing asbestos was "an urban legend."⁴⁷

3M Co., No. 3:14-CV-1096-J-39JBT, 2016 WL 3946802, at *6 (M.D. Fla. June 21, 2016); *Tyre v. CSC Transp., Inc.*, No. 16-2002-CA-4837, 2003 WL 26474173, at *1-4 (Fla. Cir. Ct. Sept. 24, 2003); *Ball v. Consol. Rail Corp.*, 142 Ohio App. 3d 748, 758-59, 756 N.E.2d 1280, 1288 (Ohio App. 2001); *Grigg v. Allied Packing & Supply Inc.*, No. RG12 629580, 2013 WL 8103870, at *2 (Cal. Super. Ct. Mar. 12, 2013); *In re Asbestos Pers. Injury Litig.*, No. 03-C-9600, 2009 WL 10696863, at *5 (W. Va. Cir. Ct. Feb. 20, 2009).

⁴⁴ *In re Lamar Cty. Order*; *see also In re Garlock Sealing Techs.*, 504 B.R. 71.

⁴⁵ (Longo 2/7/19 *Leavitt* Tr. 170:24-171:6; Dep. of William E. Longo, Ph.D. 35:2-36:16, *Herford v. AT&T*, No. BC646315 (Cal. Super. Ct. Aug. 23, 2017) ("Longo *Herford* Dep. Vol. I") (attached as Ex. E4 to Tersigni Cert.); Tr. 1841:26-1842:15, *Anderson v. Borg-Warner Corp.*, No. BC666513 (Cal. Super. Ct. May 15, 2018) (attached as Ex. E20 to Tersigni Cert.).)

⁴⁶ (Dep. of William E. Longo, Ph.D. 155:20-23, *Starkweather v. ACandS, Inc.*, No. 00-6030 (Mass. Super. Ct. July 18, 2002) (attached as Ex. E7 to Tersigni Cert.).)

⁴⁷ (*Id.* 155:10-17; *see also* Dep. of William E. Longo, Ph.D. 106:11-19, *In re Kelvin Manbodh Asbestos Litig.*, No. 324/1997 (V.I. Terr. Ct. May 28, 2002) (attached as Ex. E5 to Tersigni Cert.) ("We've looked. We have not found it.").)

Not a single public health organization or governmental body – U.S. or international – has ever asked Dr. Longo or his lab to analyze talc for asbestos.⁴⁸ Drs. Longo and Rigler have never published their methodology for testing talc for asbestos, nor have they published any papers – peer-reviewed or otherwise – related to talc at all.⁴⁹

Drs. Longo and Rigler ran no tests themselves.⁵⁰ The analysts employed by Drs. Longo and Rigler tested 49 relevant samples from bottles of the Products.⁵¹ In conducting their tests, Drs. Longo and Rigler call *every* amphibole particle “asbestos” that has an aspect ratio greater or equal to 5:1, a length greater or equal to .5 microns,⁵² and parallel sides.⁵³ This is despite the fact that it is possible that “non-asbestos tremolite . . . just so happens to break into a piece” that is “over five

⁴⁸ (Dep. of William E. Longo, Ph.D. (“Longo Dep.”) 112:20-22, 113:5-10, Feb. 5, 2019 (attached as Ex. B48 to Tersigni Cert.); Rigler Dep. 31:12-17.)

⁴⁹ (Longo 2/7/19 *Leavitt* Tr. 173:13-15; Rigler Dep. 37:14-17, 38:7-10.)

⁵⁰ (Longo Dep. 259:19-21, 261:5-8; Rigler Dep. 13:6-15; 20:14-19.)

⁵¹ Seven of the 56 samples contained Korean talc, which is unlikely to have been in products used by plaintiffs in the MDL, and these samples are therefore excluded from the analysis. (Although Dr. Longo’s report states that 57 bottles were tested, the underlying data only reveal 56.)

⁵² A micron (or “micrometer”) is unit of measurement used at the microscopic level that represents one one-thousandth of a millimeter. As a point of comparison, a red blood cell is about 7 microns wide on average. MARY LOUISE TURGEON, CLINICAL HEMATOLOGY: THEORY AND PROCEDURES 100 (2004).

⁵³ (Longo Dep. 70:12-19; 2d Suppl. Longo Rep. at 12.)

microns long” and “has more than a 5-to-1 aspect ratio.”⁵⁴ While Dr. Longo acknowledges he would not “*call* that asbestos,” he still would “write down in [his] report *asbestos* when [identifying] what that was.”⁵⁵

Even ignoring the distinction between asbestiform and nonasbestiform minerals, Drs. Longo and Rigler only purport to find miniscule amounts of “asbestos” in 32 of the 49 relevant samples they tested. The percentage of asbestos by weight they report ranges from .0092% at the high end (9.2 *thousandths* of a percent) to .0000033% (3.3 *millionths* of a percent) at the low end.⁵⁶ Their median bottle was .000017%.⁵⁷

In over half of the 49 samples (27 of them), the analysts employed by Drs. Longo and Rigler detected only 0 or 1 *particle* they claim to be asbestos. In the median bottle, they detected only a single particle. Drs. Longo and Rigler then extrapolated from those small amounts to estimate the amount of particles per gram in the bottle as a whole. That is why it is so critical that Drs. Longo and Rigler call particles asbestos even when they are not. With respect to the median

⁵⁴ (Longo *Rimondi* Tr. Vol. I 148:13-17.)

⁵⁵ (*Id.* 148:17-25 (emphases added); *see also id.* 149:18-20 (Dr. Longo admitting he “would count it and report it in [his] reports as asbestos.”).)

⁵⁶ (Dep. of William E. Longo, Ph.D. 126:1-12, *Weirick v. Brenntag N. Am.*, No. BC656425 (Cal. Super. Ct. Apr. 17, 2019) (“Longo 4/17/19 *Weirick* Dep.”) (attached as Ex. E10 to Tersigni Cert.); 2d Suppl. Longo Rep. at 33, 41.)

⁵⁷ (Longo 4/17/19 *Weirick* Dep. 126:13-24; 2d Suppl. Longo Rep. at 36.)

bottle, for example, if the sole particle Drs. Longo and Rigler found was in fact a cleavage fragment, they would be forced to conclude that they found no evidence of asbestos contamination in that bottle.

E. Drs. Longo And Rigler Claim To Utilize Multiple Microscopic Techniques.

Drs. Longo and Rigler examined talc samples using two different microscopes: a Transmission Electron Microscope (“TEM”) and a Polarized Light Microscope (“PLM”).

Examination under TEM provides three types of information. *First*, it provides a visual image that can help determine a particle’s morphology (its size and shape). This is known as Visual TEM. *Second*, it can show patterns of dots that reflect the arrangement of the atoms of the mineral, revealing its crystal structure. This is called Selected Area Diffraction (“SAED”) and helps determine the mineral type – i.e., is it tremolite or cummingtonite? *Third*, it provides a graph that can help determine the chemical composition of the particle. This is called Energy Dispersive X-ray Analysis (“EDXA”), also called Energy Dispersive Spectroscopy (“EDS”). Although EDS can help confirm the mineral type, many minerals have very similar chemical compositions and this technique has a meaningful error rate. Talc, for example, will be almost indistinguishable from anthophyllite. It can therefore at best only provide additional confirmation of the mineral type and cannot be used independently to make that determination.

Examination under PLM – the second type of microscope – provides a uniquely colored image of the mineral’s particles. The image of the particles will show its morphology, and the color can help identify the mineral type.

F. The Science Addressing The Potential Relationship Between Asbestos And Ovarian Cancer Is Focused On Heavy Occupational Exposure And, Even In That Domain, Inconclusive.

Although studies have extensively examined asbestos in relation to diseases such as mesothelioma, “[t]he relationship between asbestos exposure and ovarian cancer is not as well understood.”⁵⁸ As IARC observed in 2012, “the published literature examining the association between asbestos exposure and cancer of the ovaries is relatively sparse.”⁵⁹ This is in part due to a “[s]mall number of cases” and the fact that far “fewer women than men have been exposed to asbestos, particularly in [the] more heavily exposed occupational settings” that have been the predominant focus of the literature.⁶⁰

Of the studies that have been done, results are mixed. The majority have *not* shown a statistically significant association between asbestos exposure and ovarian

⁵⁸ Reid et al., *Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and Meta-Analysis*, 20(7) Cancer Epidemiol. Biomarkers & Prev. 1287, 1287 (2011) (“Reid 2011”) (attached as Ex. A118 to Tersigni Cert.).

⁵⁹ IARC 2012 Monograph at 253.

⁶⁰ Reid 2011 at 1287.

cancer.⁶¹ This includes the only three studies that have examined environmental, rather than occupational, asbestos exposure: (1) a 2008 study of 2,552 women living in an asbestos mining town (SMR 1.26; 95% CI: 0.58-2.40);⁶² (2) a 2009 analysis in the same population (SIR 1.18; 95% CI: 0.45-1.91);⁶³ and (3) a 2007 study of family members of men employed at an asbestos-cement factory in Italy

⁶¹ See *id.* at 1293 fig. 1 (chart showing the 16 studies, 12 of which did not report statistically significant results); *id.* at 1294 (“The present study has shown that 4 of 14 cohort studies reported a statistically significant excess rate for ovarian cancer among women exposed to asbestos. Of the remaining 10 studies, 5 reported a tendency to excess but failed to reach statistical significance and 5 reported rates that were similar to those of their reference populations. Strong evidence of consistency was not observed among these studies, although no study reported any protective effect.”).

⁶² Reid et al., *Cancer Incidence Among Women and Girls Environmentally and Occupationally Exposed to Blue Asbestos at Wittenoom, Western Australia*, 122 Int’l J. Cancer 2337 (2008) (“Reid 2008”) (attached as Ex. A117 to Tersigni Cert.). “SMR” means “standardized mortality ratio” and reports the number of deaths attributable to disease in a study population relative to the number of such deaths expected in the broader population. (“SIR” – “standardized incidence ratio” – is a similar ratio that measures relative incidence of disease rather than mortality.) The “95% CI” reflects the 95% confidence interval. Confidence intervals are explained in greater detail in defendants’ General Causation brief, but as relevant here, a confidence interval is intended to show the range of possible ratios that reflect the true relationship between the study population and the broader population. An interval that starts below and ends above 1.0 is deemed not statistically significant because 1.0 reflects equal risk between the two groups.

⁶³ Reid et al., *Gynecologic and Breast Cancers in Women After Exposure to Blue Asbestos at Wittenoom*, 18 Cancer Epidemiol. Biomarkers & Prev. 140 (2009) (“Reid 2009”) (attached as Ex. A119 to Tersigni Cert.) (analysis of ovarian cancer incidence in the same population (SIR 1.18; 95% CI: 0.45-1.91)).

(SMR 1.42; 95% CI: 0.71-2.54).⁶⁴ Some studies examining populations that sustained *heavy occupational exposure to asbestos* (i.e., female workers in factories that made asbestos products) have shown a statistically significant association between that exposure and ovarian cancer incidence or mortality.⁶⁵

The results of these studies have been analyzed in several recent meta-analyses. One such review⁶⁶ calculated an overall SMR of 1.75 (95% CI: 1.45-2.10) across 16 studies, but cautioned that the association was potentially inflated due to other diseases, such as peritoneal mesothelioma, being misclassified as ovarian cancer on subjects' death certificates.⁶⁷ The authors of a different 2011

⁶⁴ Ferrante et al., *Cancer Mortality and Incidence of Mesothelioma in a Cohort of Wives of Asbestos Workers in Casale Monferrato, Italy*, 115 *Envtl. Health Perspectives* 1401 (2007) ("Ferrante 2007") (attached as Ex. A35 to Tersigni Cert.).

⁶⁵ See, e.g., Reid 2011 at 1291 ("Statistically significant excess mortality or incidence of cancer of the ovary was reported in 4 of the 14 cohort studies").

⁶⁶ Reid 2011.

⁶⁷ (Expert Report of H. Nadia Moore, Ph.D., D.A.B.T., E.R.T. ("Moore Rep.") at 42, Feb. 25, 2019 (attached as Ex. C19 to Tersigni Cert.)) See Reid 2011 at 1287 (explaining that many studies ascertained mortality from death certificates, "[t]he accuracy of [which] has been questioned repeatedly"; observing that it has been "particularly difficult to distinguish between peritoneal mesothelioma and ovarian serous carcinoma"), *id.* at 1291, 1294; see also Camargo et al., *Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-Analysis*, 119 *Envtl. Health Perspectives* 1211, 1215-16 (2011) ("Camargo 2011") (attached as Ex. A17 to Tersigni Cert.) (observing that "until recently it has been very difficult to distinguish pathologically between peritoneal mesothelioma and ovarian cancer" and that earlier meta-analyses concluded that they could not conclude causality despite evidence of an association because of concerns about tumor misclassification and failure to account for known risk factors).

meta-analysis “restricted to highly exposed women” reported “findings . . . consistent with the hypothesis that exposure to asbestos is associated with an increased risk of ovarian cancer.”⁶⁸ In its 2012 Monograph, IARC concluded that the evidence supports an inference that asbestos exposure causes ovarian cancer, but expressly based this conclusion “on five strongly positive cohort mortality studies of women with *heavy occupational exposure* to asbestos.”⁶⁹ The non-occupational studies, IARC observed, exhibited “positive, though *non-significant*, increases in ovarian cancer.”⁷⁰ IARC’s conclusions on this issue have been called into question by the scientific community.⁷¹

Finally, the studies finding an association between asbestos and ovarian cancer generally involve exposure to crocidolite asbestos – regarded as the most potent of the various asbestos types, a fact that IARC and the recent meta-analyses concerning asbestos and ovarian cancer have all highlighted.⁷²

⁶⁸ Camargo 2011 at 1216.

⁶⁹ IARC 2012 Monograph at 256 (emphasis added).

⁷⁰ *Id.* (emphasis added).

⁷¹ As the authors of the Reid 2011 meta-analysis suggested, “the IARC decision to determine asbestos exposure as a cause of ovarian cancer was premature and not wholly supported by the evidence.” Reid 2011 at 1294.

⁷² *See id.* at 1291 (noting that crocidolite is “the most mesotheliogenic of the asbestos fibers”); Camargo 2011 at 1215 (noting that “[c]ohorts predominately exposed to crocidolite or mixed [i.e., crocidolite and chrysotile] asbestos showed larger SMRs than did those exposed only to chrysotile asbestos”); IARC 2012 Monograph at 242 (discussing studies finding no excess mortality for cancer of the

G. Asbestos Accessory Minerals Are Not Present In The Talc Deposits Mined For Defendants' Products.

Defendants sourced the talc used for the Products from mines in Northern Italy, California, Southern Vermont and China. Talc for the Products came from the Fontane mine in Val Chisone, Italy from 1926 to 1966 (except from 1941 to 1946, when defendants partially or fully sourced talc from California).⁷³ Beginning in the 1960s, defendants began sourcing talc from the Hammondsville mine in Southern Vermont (and later, from the Argonaut, Hamm and Rainbow mines in Vermont as well).⁷⁴ Since 2003, talc for the Products has been sourced from the Zhizhua mine in Guangxi Province, Longsheng County, China.⁷⁵

Plaintiffs' geology experts – Drs. Cook and Krekeler – opine that the mines from which defendants sourced their cosmetic talc contained asbestos and that the

pharynx in amosite asbestos miners but an excess mortality rate for crocidolite miners and a higher risk rate for factory workers exposed to crocidolite than workers exposed to chrysotile); *id.* at 254-55 (relying on studies that involved crocidolite and, in some cases, also chrysotile).

⁷³ (See JNJ000085376 (attached as Ex. D3 to Tersigni Cert.); JNJTALC000294523 (attached as Ex. D5 to Tersigni Cert.).)

⁷⁴ (See JNJ_000245002-148 at 50014 (attached as Ex. D1 to Tersigni Cert.); Expert Report of Mary Poulton, Ph.D. (“Poulton Rep.”) at 4-5, Feb. 25, 2019 (attached as Ex. C32 to Tersigni Cert.).)

⁷⁵ (See Poulton Rep. at 5.) It is not generally alleged that the talc from China contains asbestos. Indeed, plaintiffs' counsel in a recent trial stated in closing argument that “[t]he China mines don't have asbestos in them.” (Trial Tr. 2891:9-14, *Henry v. Brenntag N. Am., Inc.*, No. MID-1748-17AS (N.J. Super. Ct. Law Div. Oct. 10, 2018) (attached as Ex. E24 to Tersigni Cert.).)

Products were contaminated with asbestos as a result. Dr. Cook is a Professor of Geology at Auburn University in Alabama.⁷⁶ Dr. Cook opines that the talc deposits from which defendants sourced their cosmetic talc contained chrysotile, fibrous amphiboles and fibrous talc.⁷⁷ Dr. Cook also opines that the mine practices used when sourcing the talc used in the Products were not completely effective at removing amphiboles; that the sampling and screening techniques used were not sufficient to detect the asbestiform amphiboles at the levels alleged to be present here; and that the frequency and methodology of the testing of the Products were inadequate.⁷⁸

Dr. Krekeler is an Associate Professor in the Department of Geology and Environmental Earth Science at Miami University in Ohio.⁷⁹ He opines that asbestos was present in the mines used by defendants to source cosmetic talc, that the mining practices used to source the Products were not sufficient to eliminate asbestos, and that as a result, it is “probable” that consumers of cosmetic talc were exposed to asbestos.⁸⁰

⁷⁶ (See Am. Expert Report of Robert B. Cook, Ph.D. (“Am. Cook Rep.”) at 2, Jan. 22, 2019 (attached as Ex. C2 to Tersigni Cert.).)

⁷⁷ (*Id.* at 40.)

⁷⁸ (*Id.* at 2-3.)

⁷⁹ (Expert Report of Mark Krekeler, Ph.D. (“Krekeler Rep.”) at 1, Nov. 16, 2018 (attached as Ex. C31 to Tersigni Cert.).)

⁸⁰ (*Id.* at 1.)

ARGUMENT

I. DRS. LONGO AND RIGLER’S REDEFINITION OF “ASBESTOS” TO INCLUDE NONASBESTIFORM CLEAVAGE FRAGMENTS SHOULD BE EXCLUDED.

Although Drs. Longo and Rigler purport to have identified asbestos in 34 of 56 historical containers of the Products using a variety of different types of testing, they were only able to do so by redefining asbestos. As explained above, the universally accepted definition of asbestos excludes nonasbestiform cleavage fragments. Drs. Longo and Rigler pay lip service to that distinction and then throw legitimate science out the window, simply calling every amphibole they identify that meets their “counting criteria” – including nonasbestiform cleavage fragments – “asbestos.” This is particularly egregious because Drs. Longo and Rigler pass their results to PSC epidemiologists, oncologists, biologists and toxicologists who opine on studies in their respective disciplines that address health effects of *asbestos*, not “asbestos” as redefined by Drs. Longo and Rigler. This cannot pass muster under *Daubert*.

A. Even Plaintiffs’ Experts Admit That Only Asbestiform Minerals Can Be Asbestos.

There is not, and cannot be, any bona fide dispute about the definition of asbestos. It is always defined in the same way: as the *asbestiform* version of six regulated minerals. *Supra* Background § A. Given this undisputed definition of asbestos, it is also undisputed that nonasbestiform cleavage fragments are not

asbestos. *Supra* Background § B. Dr. Longo himself has repeatedly acknowledged this critical distinction. He has stated that “[i]f it’s a cleavage fragment it is not asbestos.”⁸¹ And, critically, he has gone so far as to concede that nonasbestiform minerals do not magically transform into asbestos when broken into tiny pieces – even if those tiny pieces have the same dimensions as an asbestos fiber.⁸²

B. Plaintiffs’ Experts Admit That They Utilize Methodologies That Do Not Distinguish Between Asbestos And Non-Asbestos Minerals.

Although they purport to accept that cleavage fragments broken into tiny pieces *are not asbestos*, Drs. Longo and Rigler have devised a methodology that “would count it and report it in [their] reports as asbestos” *anyway*.⁸³ This brazen attempt to evade the undisputed definition of asbestos is entirely unfounded.

1. There is only one “regulatory definition” of asbestos and it distinguishes between asbestos and nonasbestiform cleavage fragments.

Drs. Longo and Rigler’s attempt at misdirection begins by drawing a nonsensical distinction between what they term the “geological definition” of asbestos and what they term a broader “regulatory” or “health” definition.⁸⁴ Yet,

⁸¹ (Longo *Rimondi* Tr. Vol. I 142:13.)

⁸² (*Id.* 147:23-148:2.)

⁸³ (*Id.* 149:18-20.)

⁸⁴ (*See, e.g.*, 2d Suppl. Longo Rep. at 12, 25; *cf.* Dyar Rep. at 12-13.)

there is no new and different definition of “asbestos” in the regulations of the numerous health-focused agencies to define the term, like the FDA, OSHA and IARC. Thus, the contrast Drs. Longo and Rigler attempt to draw is contradicted by the universal regulatory definition of asbestos set forth above: the *asbestiform* version of six regulated minerals. *See supra* Background § A (citing, inter alia, 15 U.S.C. § 2642; 40 C.F.R. §§ 61.141, 763.83). That this definition is unfavorable to plaintiffs because it distinguishes between asbestos and nonasbestiform cleavage fragments does not give Drs. Longo and Rigler license to pretend it doesn’t exist.

In any event, Drs. Longo and Rigler *accept this definition of asbestos* (even if they later try to dismiss it). Having accepted this definition of asbestos – because there is no legitimate ground to dispute it – Drs. Longo and Rigler’s transparent attempts to run away from it render their methods fundamentally unreliable and inadmissible out of the gate. *See In re Lamar Cty.* Order (excluding Dr. Longo’s testimony because “the methodologies claimed in the MAS tests were not followed”); *see also, e.g., Ortiz v. Yale Materials Handling Corp.*, No. CIV 03-3657FLW, 2005 WL 2044923, at *9 (D.N.J. Aug. 24, 2005) (Wolfson, J.) (excluding expert who “relied on study that actually supports defendant’s position”); *Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 268-69 (2d Cir. 2002) (affirming exclusion of expert who “failed to apply his own methodology reliably”); *Truck Ins. Exch. v. MagneTek, Inc.*, 360 F.3d 1206, 1213

(10th Cir. 2004) (affirming exclusion of expert who “did not meet the standards of fire investigation [he] himself professed he adhered to”); *Wessmann v. Gittens*, 160 F.3d 790, 805 (1st Cir. 1998) (same).⁸⁵

2. **The regulatory procedures for quantifying asbestos after it has been identified do not justify ignoring the definition of asbestos.**

Because their first attempt at redefinition is inconsistent with the regulatory consensus and their own concessions, Drs. Longo and Rigler next act as though “asbestos” is every amphibole particle that has an aspect ratio greater or equal to 5:1, a length greater or equal to .5 microns, and parallel sides.⁸⁶ (Note that this definition sweeps in minerals that *cannot* be asbestos, which Dr. Longo

⁸⁵ *Accord, e.g., United States v. Tuzman*, No. 15 CR. 536 (PGG), 2017 WL 6527261, at *16-17 (S.D.N.Y. Dec. 18, 2017) (excluding expert who did not “provide[] any justification for [his] substantial deviations from the methodology he claims to have followed”); *Disabled in Action v. City of N.Y.*, 360 F. Supp. 3d 240, 244-47 (S.D.N.Y. 2019) (excluding expert who “failed to follow his own chosen methodology”); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 688 (S.D. W. Va. 2014) (“Vigorous adherence to protocols and controls are the hallmarks of ‘good science.’”); *Rimbert v. Eli Lilly & Co.*, No. CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 (D.N.M. July 21, 2009) (“Courts have excluded experts’ opinions when the experts depart from their own established standards or the standards followed in their field.”), *aff’d*, 647 F.3d 1247 (10th Cir. 2011).

⁸⁶ (See 2d Suppl. Longo Rep. at 12 (“Amphibole fibers or bundles with substantially parallel sides and an aspect ratio of 5:1 or greater, and at least 0.5 [micrometers] in length were counted as regulated asbestos”); *id.* at 13 (“All amphibole fibers/bundles that meet the above-stated size criteria were recorded on . . . structure count bench sheets for each sample.”).)

concedes.⁸⁷) Drs. Longo and Rigler reach this puzzling result by deliberately confusing the definition of asbestos and “*counting criteria*.”

In brief, certain standards govern how analysts should count asbestos fibers after they have been identified; Drs. Longo and Rigler refer to these as “standard . . . counting rules,” citing for support, among other things, the Asbestos Hazard Emergency Response Act (“AHERA”) regulations.⁸⁸ But Drs. Longo and Rigler ignore the text of that representative rule, as well as the context in which it was developed, in the way that they use it.⁸⁹ This methodological failing renders their purported identification of *asbestos* wholly unreliable.

The AHERA counting rules are found in Appendix A to 40 C.F.R. § 763. Those regulations define a *fiber* as “[a] structure greater than or equal to 0.5 [micrometers] in length with an aspect ratio (length to width) of 5:1 or greater and having substantially parallel sides.” 40 C.F.R. § 763 app. A § II.A.9; *see also id.* § II.F.9.a.i. By citing this language in their Report, Drs. Longo and Rigler act as though this is AHERA’s definition of *asbestos*. It is not. These very same AHERA regulations define *asbestos* consistent with its universally accepted definition: the *asbestiform* varieties of the six regulated minerals. 40 C.F.R.

⁸⁷ (See Longo Dep. 72:1-18.)

⁸⁸ (See 2d Suppl. Longo Rep. at 12.)

⁸⁹ According to Dr. Longo, all of the standards he invokes “have the same counting rules.” (Longo Dep. 220:15-16.)

§ 763.83. Thus, the fact that a particle meets this definition under the counting criteria means simply that it is a fiber; it doesn't provide any information about *what kind of fiber it is*. Thus, a different portion of the AHERA counting rules – one Drs. Longo and Rigler ignore – addresses the issue of identifying the fiber. What AHERA states “shall be recorded on the count sheet” is an “*asbestos* fiber.” Appendix A § II.F.9.a (emphasis added). And, again, AHERA defines asbestos as the *asbestiform* varieties of the six regulated minerals. 40 C.F.R. § 763.83.

It is also critical to consider the context in which these rules are applied. AHERA relates to remediation, i.e., the process of removing asbestos from schools and other environments where it is known to be present. *See, e.g.*, 15 U.S.C. § 2641(b). In that situation – for example, removing asbestos-containing insulation from a school – *there is no dispute that the material being removed is asbestos as opposed to a nonasbestiform cleavage fragment*. When the presence of asbestos is known and the only question is how much, there is no need to first confirm the presence of asbestos. In this context, it is unsurprising that the counting rules do not include a separate, explicit step directing the analyst to distinguish asbestiform fibers from nonasbestiform cleavage fragments.⁹⁰ But the fact that this step does

⁹⁰ To the extent AHERA sets out a precautionary strategy to ensure maximum protection of human health, that regulatory decision is not a substitute for the rigorous analysis required of expert testimony. *See, e.g., In re Zicam Cold Remedy Mktg., Sales Practices & Prods. Liab. Litig.*, No. 09-md-2096-PHX-FJM, 2011

not appear *in the counting rules* (which are applicable when one has already determined that asbestos is present) does not mean that no such step is required where, as here, the presence of asbestos is *disputed*. Indeed, AHERA *does* require such a step; it just is not listed in the counting rules and is instead part of the process for identifying asbestos *before* the counting rules are implicated. *See, e.g.*, 40 C.F.R. § 763.87(b) (citing Appendix E).

Imagine the various criteria one might have for counting poisonous mushrooms. For a field already known to be full of poisonous mushrooms, the counting criteria could be “fungus with a large cap, and a stem.” But the same criteria would be useless where the presence of poisonous mushrooms could not be assumed. In that situation, one would need to add a criterion to test for toxicity. In neither case is the definition of “poisonous mushroom” different, even though the *counting criteria* are vastly different.

Drs. Longo and Rigler’s attempt to import the counting rules into this context fails the *Daubert* test miserably; it is an unreliable method because it is simply not designed to answer the question at issue. A central consideration under

WL 798898, at *10 (D. Ariz. Feb. 24, 2011) (agency’s “prevention-oriented” standards are “materially different” from *Daubert*); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002) (agencies employ a risk-utility analysis distinct from the scientific standard demanded by a court); *cf. Hanson*, 353 F. Supp. 3d at 1281 (steps that do not distinguish asbestiform from nonasbestiform particles are “sufficient for regulatory action but not anticipated litigation”).

Daubert is “fit,” consisting of “the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.” *In re Paoli R.R. Yard PCB Litig.* (“*Paoli II*”), 35 F.3d 717, 743 (3d Cir. 1994). An “expert’s testimony must be relevant for the purposes of the case and must assist the trier of fact,” *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 321 (3d Cir. 2003), keeping in mind that “scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes,” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993).

Under this framework, it would clearly be impermissible for Drs. Longo and Rigler to import a methodology developed for identifying the amount of asbestos known to be present to a context where the entire point of the analysis is to determine whether or not asbestos is present in the first instance; it fails to answer the relevant question and is thus inherently unreliable. *See, e.g., Schepise v. Saturn Corp.*, No. CIV.A. 94-385(MLP), 1997 WL 897676, at *17 (D.N.J. July 30, 1997) (Wolfson, J.) (criticizing reliance on studies conducted “in entirely different settings” from that at issue); *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 667-68 (D.N.J. 2008) (expert’s (mis)use of statements by the CDC and FDA lacked requisite fit due to different assumptions and factual contexts underlying those statements from the litigation at hand); *Habecker v. Clark Equip.*

Co., 36 F.3d 278, 290 (3d Cir. 1994) (accident reconstruction properly excluded where it failed to replicate conditions and thus did “not ‘fit’ the facts of th[e] case”).

But what Drs. Longo and Rigler did is even worse than simply trying to import inapposite rules. They misrepresent what the counting rules do and given how much more common nonasbestiform amphiboles are than asbestiform amphiboles, *see supra*, the failure to distinguish the two leads to particularly misleading results.

Drs. Longo and Rigler use a methodology that classifies particles as asbestos *even when those particles are not asbestos*. Their overinclusive approach renders any conclusion that the particles they found were actually asbestos unreliable and speculative. *Hanson*, 353 F. Supp. 3d at 1285 (excluding expert testimony purporting to identify asbestos where the methodology used would also identify particles that were not asbestos). An expert must be able to show, rather than merely assume or guess, that he has found what he is looking for in tested material. *E.g., Finestone v. Fla. Power & Light Co.*, No. 03-14040-CIV, 2006 WL 267330, at *12 (S.D. Fla. Jan. 6, 2006) (excluding expert who assumed that a particular type of radioactive isotope was present in the tested material when available evidence demonstrated it was not), *aff’d*, 272 F. App’x 761 (11th Cir. 2008) (per curiam); *accord Ortiz*, 2005 WL 2044923, at *9-10 (“mere[] unsupported

speculation” is inadmissible). Drs. Longo and Rigler cannot justify their overinclusive redefinition of asbestos on the basis of a nonsensical “regulatory definition” of asbestos when the regulations universally define asbestos as an *asbestiform* mineral and exclude nonasbestiform cleavage fragments. Counting *fibers* instead of *asbestos* fares no better because it is not responsive to the question that they are purporting to answer. In sum, Drs. Longo and Rigler’s desperate attempts to evade a definition of asbestos that they purport to accept flies in the face of the basic reliability and fit that *Daubert* requires and requires exclusion of Drs. Longo and Rigler’s testimony purporting to identify “asbestos.”

C. Drs. Longo And Rigler’s Redefinition Of Asbestos Is At Odds With Plaintiffs’ Causation Expert Testimony.

Setting aside the fact that Drs. Longo and Rigler’s decision to count nonasbestiform cleavage fragments as asbestos has no basis in science, it is inadmissible for a separate reason: It is wholly unrelated to the theories of causation espoused by plaintiffs’ expert witnesses. The fact that Dr. Longo is applying a different definition of asbestos than plaintiffs’ causation witnesses evinces a lack of fit that warrants exclusion of this inapposite evidence under *Daubert*.

Plaintiffs’ causation experts, who have their expertise in various health fields and are not geologists or material scientists, rely on Drs. Longo and Rigler’s

various litigation reports as identifying *asbestos* in talc.⁹¹ As explained in detail above, Drs. Longo and Rigler’s analysis sweeps in both asbestos and nonasbestiform cleavage fragments, calling the latter “asbestos” even though it is not. When plaintiffs’ experts describe the health implications of the purported asbestos contamination in talc, however, they almost universally invoke IARC’s definition and evaluation of asbestos.⁹² The same organization has explained that the six regulated minerals “when asbestiform, . . . constitute asbestos and, when not asbestiform, they are referred to as mineral fragments or cleavage fragments.”⁹³

As a result, plaintiffs’ other experts are using a different definition of asbestos in forming their conclusions about hazards to human health than Dr. Longo used to purportedly quantify the concentration of asbestos in the bottles. This mismatch requires exclusion of Drs. Longo and Rigler’s purported

⁹¹ (See, e.g., Expert Report of Shawn Levy, Ph.D. (“Levy Rep.”) at 15, Nov. 16, 2019 (attached as Ex. C39 to Tersigni Cert.); Expert Report of Anne McTiernan, M.D., Ph.D. (“McTiernan Rep.”) at 57, 81-82, Nov. 16, 2018 (attached as Ex. C7 to Tersigni Cert.); Expert Report of Patricia G. Moorman, M.S.P.H., Ph.D. (“Moorman Rep.”) at 35, Nov. 16, 2018 (attached as Ex. C35 to Tersigni Cert.); Expert Report of Jack Siemiatycki, M.Sc., Ph.D. (“Siemiatycki Rep.”) at 30, Nov. 16, 2018 (attached as Ex. C21 to Tersigni Cert.); Expert Report of Rebecca Smith-Bindman, M.D. (“Smith-Bindman Rep.”) at 14, 44, Nov. 15, 2018 (attached as Ex. C36 to Tersigni Cert.).)

⁹² (See, e.g., Levy Rep. at 15; McTiernan Rep. at 57; Moorman Rep. at 35; Siemiatycki Rep. at 29; Smith-Bindman Rep. at 5, 14-15.)

⁹³ IARC 2010 Monograph at 277; see also *id.* (defining asbestos as the six regulated minerals when they “occur in the *asbestiform* habit”) (emphasis added).

identification of asbestos, as they use a different definition from the medical and scientific literature on which the other experts for the plaintiffs rely. *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 548-50 (W.D. Pa. 2003) (collecting cases that “evidence concerning the effect of allegedly ‘similar’ chemicals on the body cannot substitute for direct evidence about the drug in question”).

II. DRS. LONGO AND RIGLER’S MICROSCOPY FAILS TO FOLLOW ACCEPTED, REPRODUCIBLE METHODOLOGIES AND SHOULD BE EXCLUDED.

Drs. Longo and Rigler analyze the Products for asbestos contamination using four separate microscopic techniques. For each, they use methodologies that cannot survive exclusion under *Daubert*. Drs. Longo and Rigler deliberately employ methodologies that are not verifiable or reproducible, often designed deliberately so, and have chosen methodologies that are useless for identifying asbestos contamination, as each ultimately conceded under deposition.

Drs. Longo and Rigler state that they follow ISO 22262.⁹⁴ ISO stands for the International Organization for Standardization, which is a worldwide federation of 164 national standards bodies.⁹⁵ It counts among its members the American National Standards Institute (“ANSI”), which represents the interests of more than

⁹⁴ (2d Suppl. Longo Rep. at 9-12.)

⁹⁵ International Organization for Standardization, *All About ISO*, <https://www.iso.org/about-us.html> (last visited May 4, 2019) (attached as Ex. A77 to Tersigni Cert.).

125,000 companies and 3.5 million professionals.⁹⁶ The ISO 22262 standard has two parts that are material to this litigation. There is Part 1 (ISO 22262-1), which specifies the “procedures for collection of samples and qualitative analysis of commercial bulk materials for the presence of asbestos.”⁹⁷ And there is Part 2 (ISO 22262-2), which “specifies procedures for quantification of asbestos mass fractions below approximately 5%.”⁹⁸

Section A below addresses Drs. Longo and Rigler’s use of “visual TEM,” a methodology that provides a two-dimensional image of a particle. **Section B** addresses their use of “SAED,” a methodology that provides information about the crystal structure of a particle. **Section C** addresses their use of “EDXA,” a methodology that provides information about the chemical composition of a particle. **Section D** addresses their use of “PLM,” which provides information about mineral type and morphology.

⁹⁶ International Organization for Standardization, *ANSI*, <https://www.iso.org/member/2188.html> (last visited May 4, 2019) (attached as Ex. A78 to Tersigni Cert.).

⁹⁷ ISO 22262-1 at vi.

⁹⁸ ISO 22262-2 at 1.

A. Visual TEM: Drs. Longo And Rigler’s Opinions Should Be Excluded Because Their Methodology Has No Objective Standards And Not Even They Can Get Consistent Results.

Although Drs. Longo and Rigler’s methodology does not require any distinction between asbestos and nonasbestiform cleavage fragments, they claim that “bundles” of amphibole particles must be asbestiform and can properly be called “asbestos.” The problem with this approach is that Drs. Longo and Rigler have no reliable way of identifying a “bundle,” demonstrated by the fact that *their own analysts* cannot consistently distinguish between “bundles” and “fibers.” This lack of reproducibility requires exclusion under *Daubert*.

1. Background: Visual TEM provides a two-dimensional image of a specimen.

A TEM uses beams of electrons to take a type of picture of a specimen.⁹⁹ That is, a TEM can produce a visual, two-dimensional image of a specimen showing its size and shape. Here, for example, is a TEM image from Drs. Longo and Rigler’s report:¹⁰⁰

⁹⁹ (Transcript of Proceedings (A.M. Session) 1301:5-1302:3, *Herford v. AT&T Corp.*, No. BC646315, JCCP 4674 (Cal. Super. Ct. Oct. 25, 2017) (attached as Ex. E19 to Tersigni Cert.).)

¹⁰⁰ (Report of William E. Longo Ph.D. & Mark W. Rigler, Ph.D. (“Longo Rep.”) at 403, Nov. 14, 2018 (attached as Ex. C41 to Tersigni Cert.).)

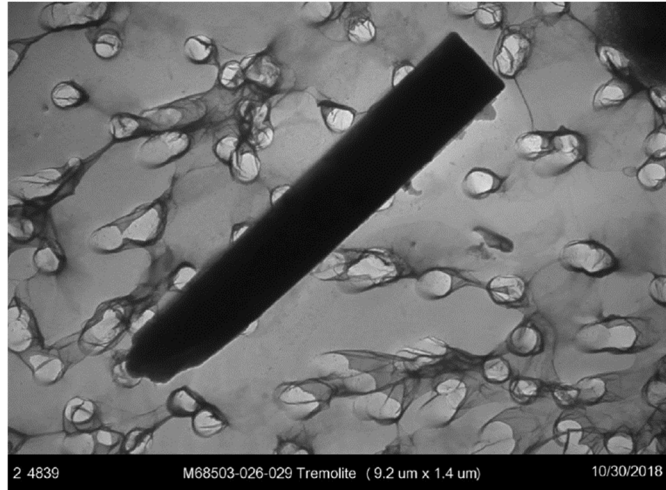


Figure 3: TEM image of tremolite

A TEM image essentially shows a silhouette of the structures it detects.

2. **Drs. Longo and Rigler’s identification of “bundles” is fundamental to their visual TEM analysis.**

Dr. Longo has long acknowledged that visual TEM analysis cannot determine whether a single “fiber” is asbestiform or nonasbestiform.¹⁰¹ This concession is unsurprising; the testing methods that Dr. Longo uses (like ISO 13794, for determining asbestos in air) explicitly state that the method cannot distinguish between individual fibers of asbestos and nonasbestiform particles.¹⁰²

Dr. Longo started disclosing his testing of the Products in cases against the defendants in 2017 and 2018. In that first tranche of testing, Dr. Longo’s analysts

¹⁰¹ (See, e.g., Dep. of William E. Longo, Ph.D. 45:10-13, *Anderson v. Borg-Warner Corp.*, No. JCCP 5674/BC666513 (Cal. Super. Ct. Mar. 29, 2018) (“Longo 3/29/18 *Anderson* Dep.”) (attached as Ex. E3 to Tersigni Cert.) (“[T]here’s no way to tell with just TEM, if you’re looking at a single fiber, if it’s asbestiform or not.”); Longo *Herford* Dep. Vol. I 111:12-20 (same); Longo *Rimondi* Tr. Vol. I 164:18-21, 172:18-22 (same).)

¹⁰² (E.g., Longo Dep. 221:14-222:3.)

characterized 53% of the suspected asbestos particles as “fibers.”¹⁰³ When Dr. Longo would present these results at trials, he was subjected to cross-examination about the limitations described above. Fast forward to the testing at issue in this case, and suddenly the percentage of particles Dr. Longo classifies as “fibers” has dropped precipitously from 53% to **4%** – and **96%** of the particles are purportedly “bundles,” referring to multiple “fibers” clumped together.¹⁰⁴ The motive for this shift is clear: If the particles are bundles of fibers, Dr. Longo argues that then they *must* be asbestiform.¹⁰⁵ But as explained below, the “methodology” that they have developed for identifying bundles lacks objectivity and is inconsistent, amounting to wholly unreliable *ipse dixit*. As a result, the purported identification of “bundles” should be excluded.

3. Drs. Longo and Rigler lack an objective methodology.

The problem with Drs. Longo and Rigler’s methodology for identifying “bundles” is simple: There is no methodology. In fact, they fail to employ generally accepted visual cues for what constitutes a bundle of asbestos fibers.

¹⁰³ (Tr. 153:11-14, *Leavitt v. Johnson & Johnson*, No. RG17882401 (Cal. Super. Ct. Feb. 14, 2019) (attached as Ex. E26 to Tersigni Cert.).)

¹⁰⁴ (2d Suppl. Longo Rep. at 25.)

¹⁰⁵ (*Id.*)

As defendants' expert Dr. Dyar explains, "[b]undles occur as separable groups of parallel fibers with splayed ends and matted masses" as seen here:¹⁰⁶

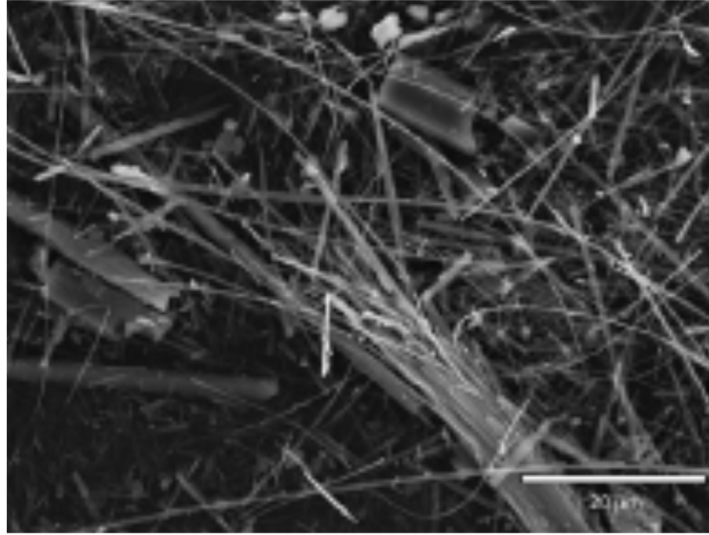


Figure 4. Image of tremolite bundle of asbestiform particles.

This is consistent with the same ISO standard on which Dr. Longo relies, which similarly indicates that “fibre bundles displaying splayed ends” are more likely to be asbestiform.¹⁰⁷ This means, as Dr. Dyar puts it, “[a]t the end of a bundle, the fibers generally bend out like the straws at the end of a broom.”¹⁰⁸

Unlike Dr. Dyar, Drs. Longo and Rigler have been unable to articulate any objective criteria to be used in their visual analysis.¹⁰⁹ For example, when asked

¹⁰⁶ (Dyar Rep. at 53.)

¹⁰⁷ ISO 22262-1 at 22.

¹⁰⁸ (Dyar Rep. at 54.)

¹⁰⁹ Dr. Longo claims to have “internal MAS-generated reference samples for TEM to identify asbestos.” (Longo Dep. 42:9-12.) If these exist, the PSC decided

how he could tell that the image he was looking at was a bundle of fibers as opposed to a single fiber, he answered simply: “Because I can see them.”¹¹⁰ And Dr. Longo has repeatedly acknowledged that the inquiry is subjective, indicating that “the analyst is ultimately making the decision if it is a single fiber or a bundle.”¹¹¹ In other words, whatever Dr. Longo says goes.

A “methodology” that consists of the subjective interpretation of pictures “completely detached from any objective criteria” poses a tremendous risk of results-oriented *ipse dixit*. *United States v. Williams*, No. 3:13-CR-00764-WHO-1, 2017 WL 3498694, at *10 (N.D. Cal. Aug. 15, 2017) (criticizing expert opinion as “untestable”). That is clear from Drs. Longo and Rigler’s results. The particles identified as bundles are slab-like, with no splayed ends, like the following:¹¹²

not to produce them. (*See id.* 42:16-17.) And in any event, they fail to produce reliable results.

¹¹⁰ (Longo Dep. 250:14-16.)

¹¹¹ (*Id.* 57:3-5; *see also* Longo *Rimondi* Tr. Vol. I 107:12-13, 107:18-19, 171:21-22 (same).)

¹¹² (Dyar Rep. at 56.)

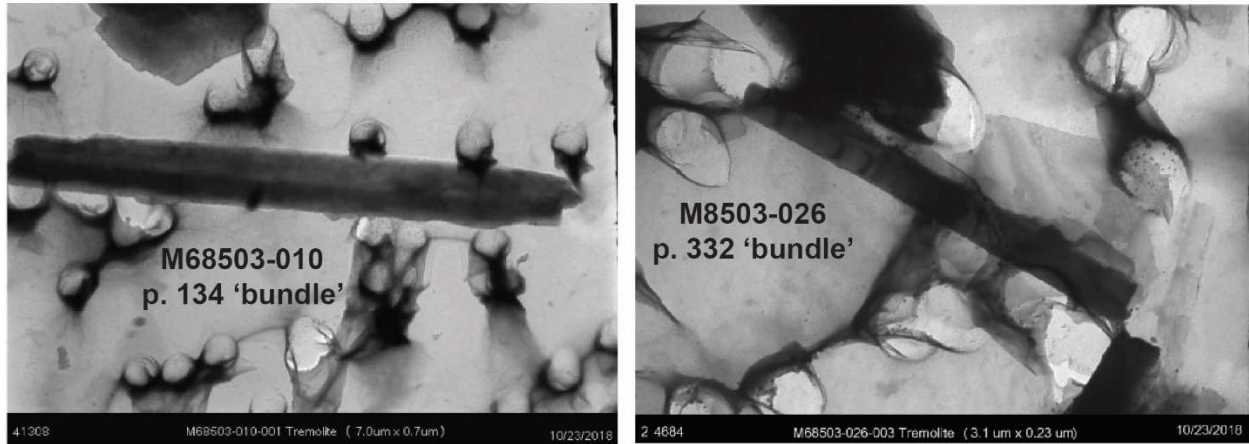


Figure 5. Images of particles claimed to be bundles.

More fundamentally, their classifications have changed over time. Compare Dr. Longo's classifications of structures in his March 2018 report with that of similar structures in his November 2018 report issued for this proceeding:¹¹³

¹¹³ (On left: Suppl. Expert Report & Analysis of Johnson & Johnson Baby Powder and Valeant Shower to Shower Talc Products for Amphibole Asbestos at 32, 33, 55, 106, 617, 634, Mar. 11, 2018 (attached as Ex. E14 to Tersigni Cert.). On right: Longo Rep. at 240, 248, 585, 595, 1662, 1676 (MDL Report).)

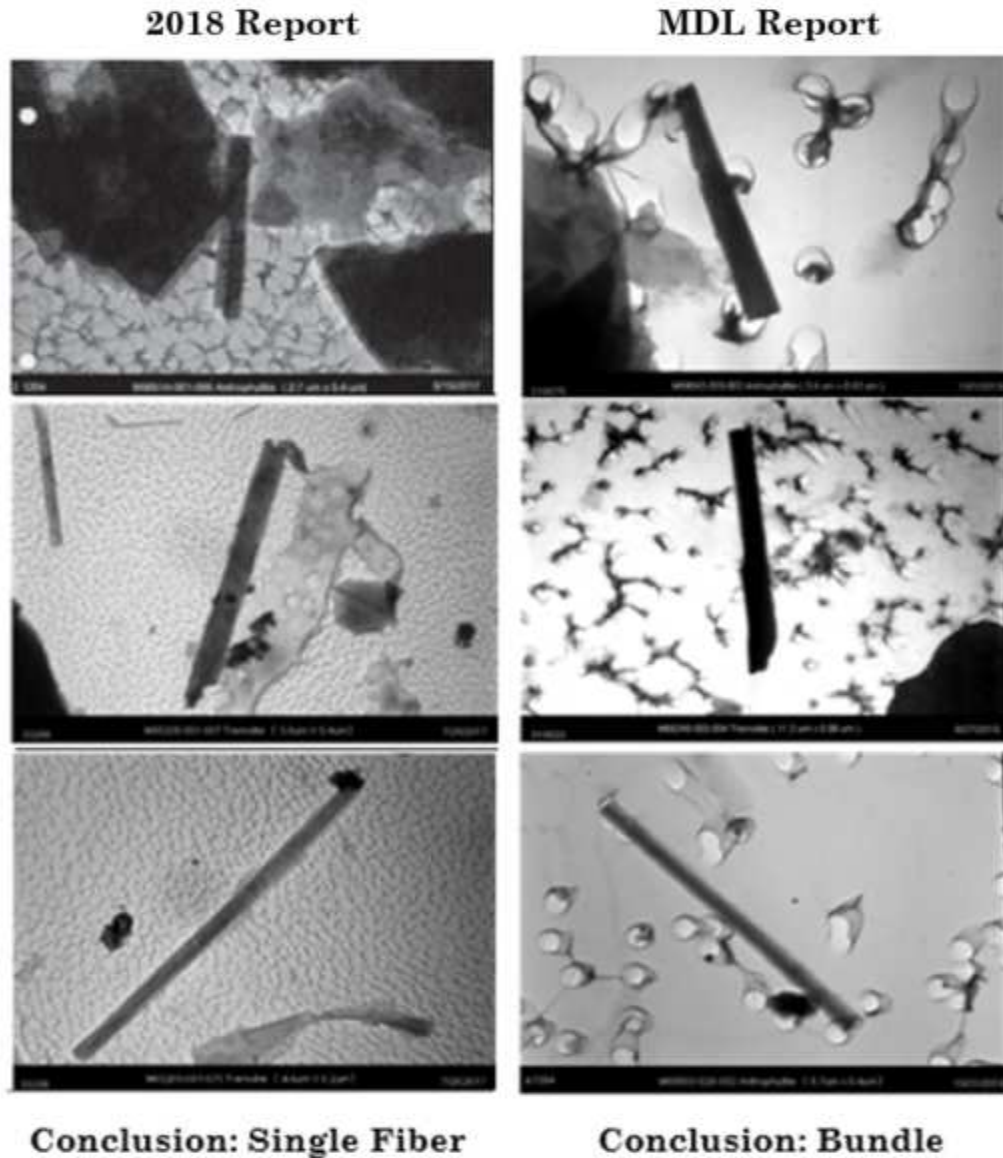


Figure 6: Comparison showing Dr. Longo's inconsistent classification of structures between reports.

Despite the obvious similarities in these images, what Dr. Longo saw changed as litigation on this issue proceeded. This unexplained “sudden reversal of opinion” alone “seriously undermines the reliability of” Drs. Longo and Rigler’s methodology. *Fireman’s Fund Ins. Co. v. Canon U.S.A., Inc.*, 394 F.3d 1054, 1059 (8th Cir. 2005).

4. **Drs. Longo and Rigler’s analysts have demonstrated that they cannot reliably differentiate “bundles” and “fibers.”**

The subjective nature of Drs. Longo and Rigler’s approach to bundles is illustrated by their own internal quality-control testing. Dr. Longo and the analysts at his laboratory cannot consistently identify a “bundle” – a fact obvious from a study *that Dr. Longo himself commissioned* on the accuracy of his methodology.

Four microscopists from Dr. Longo’s lab were asked to analyze the same TEM grid openings.¹¹⁴ They looked at the same 25 TEM “grid openings” of an off-the-shelf Johnson’s Baby Powder container that had been spiked with asbestos to reach a concentration of 0.3 percent.¹¹⁵ Among other things, the microscopists were directed to determine whether what they saw was a fiber, a bundle, or a non-detect.¹¹⁶ The idea behind this exercise was to calculate his laboratory analysts’ error rate in identifying asbestos particles in a talcum powder sample.¹¹⁷

¹¹⁴ (See MAS TEM Coefficient of Variation for Tremolite and Anthophyllite in Talc: A Quality Control Study at 1, Sept. 6, 2018 (“MAS CoV Rep.”) (attached as Ex. A92 to Tersigni Cert.)). A TEM grid opening is what one sees when peering through a TEM, separating the visual field into “grids.” (Dep. of William E. Longo, Ph.D. 56:4-56:8, *Von Salzen v. Am. Int’l Indus. Inc.*, No. BC6805786 (Cal. Super. Ct. June 27, 2018) (attached as Ex. E8 to Tersigni Cert.) (“In a TEM grid, your field of view at 200x is most of the grid openings, or 50X. At 20,000 to 25,000 your view is approximately 1/20 of the grid opening, and a grid opening is 100 microns by 100 microns.”).)

¹¹⁵ (MAS CoV Rep. at 1.)

¹¹⁶ (*Id.* at 5-12.)

¹¹⁷ (See generally MAS CoV Rep.; Longo *Rimondi* Tr. Vol. I 169:9-171:15.)

The results were staggering: The four analysts agreed *only one time*, and then only for a fiber; in other words, they never agreed on a specimen as a “bundle”:¹¹⁸

Grid Opening	(Analyst 1) Structure	(Analyst 2) Structure	(Analyst 3) Structure	(Analyst 4) Structure
A8-E2	Bundle	Fiber	Fiber	Bundle
A8-E4	Fiber	Fiber	Fiber	Fiber
A8-E5	Bundle	Bundle	Bundle	Fiber
A8-E7	Fiber	Bundle	Fiber	Fiber
A8-E8	Bundle	Fiber	Bundle	Fiber
A8-E9	Bundle	Bundle	Bundle	Fiber
A8-F2	Bundle	Bundle	Fiber	Bundle
A8-G1	Bundle	Bundle	Bundle	Fiber
A8-G4				Fiber
A8-G5		Bundle		
A8-G6	Bundle	Fiber	Bundle	Bundle

Note, this was a test to determine *consistency* – it was not a test for *accuracy*.

There is no way of confirming that even the single sample upon which all four analysts agreed was correctly identified. All that Dr. Rigler could say about this inconsistency was the nonsensical response that *all four* analysts were right *each time*.¹¹⁹ That is obviously not possible.

¹¹⁸ (See MAS CoV Rep. at 5-12; see also Rigler Dep. 177:6-189:23; Longo *Rimondi* Tr. Vol. I 171:3-11.) The amount the analysts vary is called a “coefficient of variation” or “CoV.” Dr. Longo holds out this report as proving that his analysts have a CoV of just six percent. Yet this rate only applies to whether they identified an amphibole particle *at all*. (Longo *Rimondi* Tr. Vol. I 171:11-15.) This does not capture the tremendous disagreement between the analysts as to whether a particle was a fiber or a bundle.

¹¹⁹ (Rigler Dep. 184:20-24.)

The inability of MAS analysts to replicate Dr. Longo's results and consistently agree on whether a structure is a bundle is a serious problem. "Scientific methodology today is based on generating hypotheses and testing them," which "is what distinguishes science from other fields of human inquiry." *Daubert*, 509 U.S. at 593. In other words, "reproducible testing is a hallmark of reliable science." *Rembrandt Vision Techs., L.P. v. Johnson & Johnson Vision Care, Inc.*, 282 F.R.D. 655, 667 (M.D. Fla. 2012); *see also United States v. Hebshie*, 754 F. Supp. 2d 89, 125 (D. Mass. 2010) (describing reproducibility as "the sine qua non of 'science'"). Thus "a key question" under *Daubert* is "whether [a methodology] has been tested and independently validated or replicated." *Ruffin v. Shaw Indus., Inc.*, 149 F.3d 294, 297 (4th Cir. 1998); *see also Paoli II*, 35 F.3d at 742 (describing requirement of "testability"). This means that "[s]omeone else using the same data and methods must be able to replicate the result." *Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005).

Here, Dr. Longo's "methodology" is worse than untested; it has been proven incapable of replication – and thus unreliable. The fact that even Dr. Longo's own employees "reached radically different findings and conclusions" when asked to distinguish between fibers and bundles shows that they were simply "unable to replicate [his] findings" in the way necessary to demonstrate reliability. *Ruffin*, 149 F.3d at 297-98 (affirming exclusion of expert testimony where attempts to

replicate the study had failed). For this reason alone, Dr. Longo's purported identification of "bundles" must be excluded under *Daubert*. See, e.g., *id.*; *Williams*, 2017 WL 3498694, at *10 (excluding expert testimony that "was so subjective that it could even vary between analysts at [the expert's laboratory]"); *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *13 (E.D. Pa. Feb. 1, 2001) ("Dr. Bloor could not reproduce his own results when asked to re-score the slides using his own method."); *United States v. Johnson*, 122 F. Supp. 3d 272, 330 (M.D.N.C. 2015) (excluding expert testimony because expert's subjective "methodology is seriously flawed and cannot be replicated").

The reason "an expert's testimony should be excluded if testing his methodology does not generate consistent results" is because "[i]nconsistency of results demonstrates the method is 'unreliable because it is subjective and unreproducible.'" *Soldo*, 244 F. Supp. 2d at 527 (citing *Elcock v. Kmart Corp.*, 233 F.3d 734, 747 (3d Cir. 2000)). That could not be more true here. Dr. Longo's "method" of distinguishing between fibers and bundles is a purely subjective and highly malleable inquiry. Its subjective character gives Dr. Longo license to make things up with impunity. This results-oriented *ipse dixit* cannot and does not pass muster under *Daubert*. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse*

dixit of the expert.”); *see also, e.g., Durkin v. Equifax Check Servs., Inc.*, 406 F.3d 410, 421 (7th Cir. 2005) (affirming exclusion of “untestable say-so”).

B. SAED: Drs. Longo And Rigler’s Opinions Should Be Excluded Because Their Methodology Is Scientifically Invalid And Unverifiable.

SAED provides an image of the arrangement of the atoms in a mineral. These images must be taken at particular angles, called “zone-axis orientations,” so they can be compared against the known measurements for minerals at those pre-established angles. And because the arrangement of atoms is three-dimensional, an image taken at a single orientation will not reveal enough about the shape of the atomic arrangement to uniquely identify the mineral. At least two images taken from different zone-axis orientations are necessary. Drs. Longo and Rigler *never* take images at more than one zone-axis orientation. Their results are therefore consistent with *thousands* of other minerals. Yet, they claim it identifies a specific one. At times their results are even *inconsistent* with the anthophyllite or tremolite they claim to identify.

1. Background: SAED provides information about the crystal structure.

In addition to obtaining images of particles observed, TEM can be used for SAED for mineral characterization.¹²⁰ Through SAED, the microscope gathers

¹²⁰ (Dyar Rep. at 28.) ISO 22262-1 at 64-66.

information about the crystal structure of a particle – the unique arrangement of atoms in a mineral.¹²¹ SAED produces a pattern of dots known as a “diffraction pattern” that reflects the arrangement of the atoms.¹²² Below are examples of SAED patterns for tremolite at three different orientations:¹²³

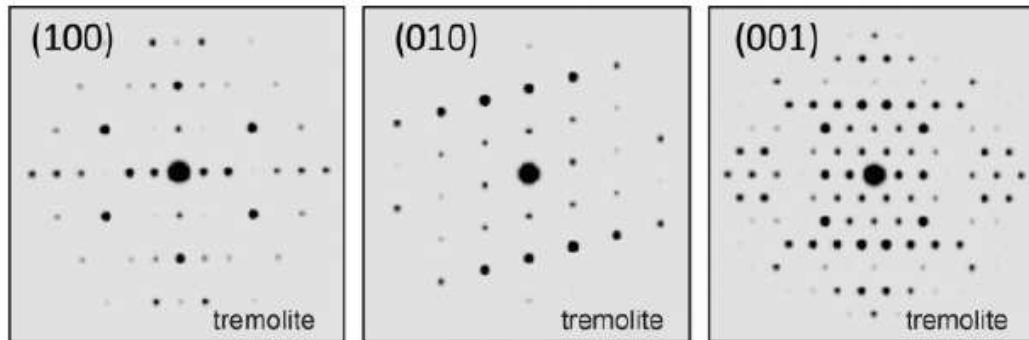


Figure 7. SAED Patterns for tremolite at three different orientations

When using an appropriate methodology, SAED *can*, on its own, determine the mineral type based on crystal structure (i.e., is it tremolite). A scientist looks at the dots in the projections obtained and measures the spacing between them (the “d-spacing”) and the angles between them, and then compares them to established measurements, often with the aid of indexing software.¹²⁴

¹²¹ (Dyar Rep. at 28.) ISO 22262-1 at 65.

¹²² ISO 22262-1 at 64-65; Brydson et al., *Analytical Transmission Electron Microscopy* 3 (2014) (“Brydson 2014”) (attached as Ex. A15 to Tersigni Cert.).

¹²³ (Dyar Rep. at 30 (adopted from Melinda Darby Dyar Ph.D. & Mickey E. Gunter Ph.D., *Mineralogy and Optical Mineralogy* fig. 15.2 (2008)).)

¹²⁴ ISO 22262-1 at 4, 64-65. (See also Dyar Rep. at 28-32.)

These images cannot be taken from just any point of view (or “orientation”). There are special types of orientations necessary to uniquely identify a mineral: zone-axis orientations. A zone axis is an area where two crystal faces intersect. Zone-axis orientations are important because the d-spacings and angles at those orientations are known for numerous minerals. Analysts are therefore capable of comparing their measurements of the unknown mineral to the known measurements at those pre-established perspectives. In order to uniquely identify a mineral by SAED, the analyst must obtain diffraction patterns from “near-exact zone axis orientations.”¹²⁵ As Drs. Longo and Rigler’s own method, ISO 22262, explains, only zone-axis diffraction patterns can be interpreted quantitatively by comparison to “known mineral structures.”¹²⁶

Additionally, a single diffraction pattern at just one zone-axis orientation will not be sufficient. To get an accurate understanding of a crystal structure’s

¹²⁵ See Yamate et al., *Methodology for the Measurement of Airborne Asbestos by Electron Microscopy* 44 (1984) (“Yamate 1984”) (attached as Ex. A158 to Tersigni Cert.) (“Since an SAED pattern may be considered as a signature of the crystal structure of the diffracting crystal . . . , the mineral giving pattern can be identified by comparison of measured and standard sets of d-spacings and interplanar angles from SAED patterns obtained in near-exact zone axis orientations. Such identifications may not be absolutely without the provisions of SAED patterns from more than one zone-axis orientation.”).

¹²⁶ See ISO 22262-1 at 64 (“ . . . only those ED patterns obtained when the fibre is oriented with a principal crystallographic axis closely parallel to the incident electron beam direction can be interpreted quantitatively. This pattern shall be referred to as a zone-axis ED pattern.”).

shape, multiple images must be taken at different zone-axis orientations.¹²⁷ This is because a crystal structure is three-dimensional. Imagine a tissue box, with each corner representing an atom. By looking at the atoms of a tissue box head on, one could determine that one side had a rectangular structure. But without taking an image from at least one other orientation, it would be impossible to get a complete picture of its shape. It could be something else entirely:



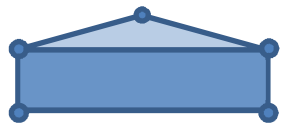

Example	Structure	SAED Pattern (Direct Angle)
Tissue Box		
Slice of Cake		

Figure 8: Illustration of inadequacy of single-point-of-view SAED patterns

SAED patterns work the same way. Except in rare circumstances, multiple zone-axis orientations are necessary to uniquely identify a mineral. In this analogy, the edges of the tissue box are the zone axes. And a zone-axis orientation would be an image taken parallel to the edge.¹²⁸

The protocols Drs. Longo and Rigler purport to have followed themselves state that taking *two* zone-axis diffraction patterns is a necessary part of a reliable

¹²⁷ (Dyar Rep. at 28-32.) ISO 22262-1 at 64-65.

¹²⁸ As ISO 22262 describes it: if a diffraction pattern is taken “parallel to the intersection edges of the crystal faces,” then the diffraction pattern is called a zone-axis diffraction pattern. ISO 22262-1 at 7.

quantitative SAED analysis.¹²⁹ The Yamate protocol – an EPA protocol for characterizing particles using SAED – has similar requirements.¹³⁰ Dr. Longo agrees that an analyst needs “[a] minimum of two, maybe three” orientations to “uniquely identify a mineral with SAED.”¹³¹

A reliable SAED analysis therefore has two components: (1) a diffraction pattern must be taken at a zone-axis orientation; and (2) multiple diffraction patterns must be taken at different zone-axis orientations. Drs. Longo and Rigler’s methodology fails both criteria.

2. MAS analysts acquired non-zone-axis orientations with results consistent with thousands of minerals.

Out of the hundreds of particles included in Drs. Longo and Rigler’s report, only 41 particles in six samples include zone-axis diffraction patterns.¹³² Of those 41 particles, 31 are identified as tremolite particles and only one is identified as an anthophyllite particle. That means that for every other particle in the report, the

¹²⁹ ISO 22262-1 at 64 (stating that a single zone-axis reading “can be insufficiently specific to permit unequivocal identification of the mineral fibre,” and that analysts should “record a different ED pattern corresponding to another zone axis”).

¹³⁰ Yamate 1984 at 56; *Hanson*, 353 F. Supp. 3d at 1287 (Yamate method “requires analysis of two zone-axis orientations because identification of a particle ‘may not be absolute’ based on SAED patterns from a single zone-axis orientation”).

¹³¹ (Longo Dep. 139:9-11.)

¹³² (See Dyar Rep. at 38, 41.)

diffraction pattern is a random, non-unique pattern that cannot uniquely identify anthophyllite or tremolite. Indeed, Dr. Longo confirmed that “[m]ost of your amphibole minerals . . . will have d-spacings in this range,”¹³³ and there are over 70 different amphibole minerals.¹³⁴

Take one representative example where the MAS analyst’s only measurement was a single d-spacing of 5.23 angstroms (a unit of measurement denoted by the symbol “Å”).¹³⁵ This would be like being told ***only*** that the distance between two random corners of an object is 5 inches and concluding: ***it must be a tissue box.***

In fact, there are ***thousands*** of minerals with one d-spacing at one orientation within 5% of 5.2 Å (5% being the range the MAS analysts used).¹³⁶ The MAS analysts failed to consider whether the measurements more closely matched those of other minerals.¹³⁷ See *Witt v. Stryker Corp. of Mich.*, 648 F. App’x 867, 873-74 (11th Cir. 2016) (affirming exclusion of expert witness testimony as “undeveloped and unreliable” where expert did not “so much as consider any alternative explanation”). Dr. Longo even admitted: “[S]ome of these

¹³³ (Longo Dep. 157:3-8.)

¹³⁴ “Amphibole,” *Encyclopedia Britannica* (2016).

¹³⁵ (Longo Dep. 156:5-14; Rigler Dep. 119:3-8.)

¹³⁶ (Dyar Rep. at 35-36.)

¹³⁷ (*Id.* at 34, 39.)

may well be cummingtonite. It's immaterial to me.”¹³⁸ This would not be the first time that the “appearance is that Dr. Longo’s studies were carried out in such a way as to produce the highest result.” *In re Garlock Sealing Techs., LLC*, 504 B.R. at 80.

In a bench trial in *Roche Palo Alto v. Ranbaxy Laboratories Ltd.*, this Court disregarded an expert’s testing because it was based on the “erroneous assumption” that the test results would “uniquely identify” the relevant compound (in a particular form) when the expert’s own testing did not establish that. No. 06-2003, 2009 WL 3261252, at *7 (D.N.J. Sept. 30, 2009) (Wolfson, J.). Drs. Longo and Rigler’s SAED testing similarly does not uniquely identify the particles as either anthophyllite or tremolite.

By not taking zone-axis orientations, Drs. Longo and Rigler deviated from the methods they purport to follow.¹³⁹ Dr. Longo has done this before. In *Lamar County Asbestos Litigation*, the court explained when excluding Dr. Longo’s opinion that “the methodologies claimed to be used by MAS in the test reports were not followed.”¹⁴⁰ In this case, MAS’ deviation rendered it impossible for them to uniquely identify anthophyllite or tremolite. In fact, their limited

¹³⁸ (Longo 4/17/19 *Weirick* Dep. 116:10-11.)

¹³⁹ *See* ISO 22262-2 at 64.

¹⁴⁰ *In re Lamar Cty.* Order at 12.

measurements would be consistent with every amphibole on the planet and potentially thousands of other minerals.

3. **In the rare times Drs. Longo and Rigler used a zone-axis orientation, it was never more than one.**

The MAS analysts who ran the SAED analysis materially deviated from the methods they purport to follow in a second regard. In the handful of instances where the MAS analysts who ran the SAED analysis acquired zone-axis diffraction patterns, they did so at no more than one zone-axis orientation. This cannot pass *Daubert* review on several levels.

As discussed above, Dr. Longo conceded – as his own protocols also state – that an analyst needs “[a] minimum of two, maybe three” orientations to “uniquely identify a mineral with SAED.”¹⁴¹

Yet, Dr. Longo also admitted that “for all the MDL bottles [he] at most took only one zone-axis orientation for the particles [he] analyzed under SAED.”¹⁴² Their report did not cite a single authority for that approach, which makes sense

¹⁴¹ (Longo Dep. 139:9-11; *see also* Rigler Dep. 108:23-109:18 (to “distinguish anthophyllite from cummingtonite with SAED alone,” “you’d have to do zone axis in a couple of different zones to tell”).)

¹⁴² (Longo 4/17/19 *Weirick* Dep. 125:1-5; *see also id.* 122:21-25 (admitting that for “no particle that [he] designated anthophyllite did [he] take more than one zone axis orientation”); *id.* 124:21-24 (same for tremolite).)

because even Drs. Longo and Rigler had to concede that analysis at a single zone axis cannot identify a mineral.¹⁴³

In *Hanson*, the expert compared “the diffraction pattern of the fiber with an SAED pattern obtained from an asbestos standard sample,” which is part of Level I of the Yamate method. 353 F. Supp. 3d at 1280. However, the expert did not perform “a quantitative SAED analysis from two different near-exact zone-axis orientations,” which is part of Yamate Level III. *Id.* at 1281. The court explained that “[z]one axis SAED is important because identification of a particle ‘may not be absolute’ based on the single zone-axis orientation at Level I.” *Id.* The court excluded the expert in part because he “chose not to perform the Yamate Level III zone-axis SAED analysis for his product testing.” *Id.* at 1286.

Drs. Longo and Rigler’s similar failure to conduct a multiple zone-axis SAED analysis is another, independent reason that their SAED methodology is unreliable and should be excluded.

¹⁴³ For some “anthophyllite” samples, the SAED analysts took two diffraction patterns, but not at two zone axes and only to disqualify the sample as being talc. (*See, e.g.*, Longo Dep. 137:18-138:6 (“Q. Okay. So for anthophyllite, where you have two axes and so like two SAED patterns, in a vacuum, do those two patterns sitting in front of you, no other information, uniquely identify what you’re looking at as anthophyllite? A. I don’t know.”).)

4. **Drs. Longo and Rigler identify particles as anthophyllite or tremolite even when the measurements are *inconsistent* with that conclusion.**

The methodological flaws discussed above show that Drs. Longo and Rigler's results were consistent with numerous other minerals, and not just anthophyllite or tremolite. In fact, the Longo-Rigler SAED methodology is so results-oriented that they will identify particles as tremolite or anthophyllite even if the results are *inconsistent* with that mineral.

Sample M68503-001 is an example.¹⁴⁴ Drs. Longo and Rigler calculated a d-spacing of 21.2 Å and identified the particle as anthophyllite. Dr. Rigler said that means “in the peer-reviewed literature one would find that a . . . zone spacing of 21.2 will correspond uniquely to anthophyllite.”¹⁴⁵ But Dr. Longo acknowledged that at *no* zone-axis orientation will an anthophyllite pattern have a d-spacing even “close to 21.2” in the only published material he was aware of with that information.¹⁴⁶ Just as Dr. Longo testified that he will call something “asbestos” even when it's not, he will identify a mineral as “anthophyllite,” even when it's not.

¹⁴⁴ (Diffraction Verification M68503 at 3 (MAS Job # M68503-001-001 diff 2) (attached as Ex. A27 to Tersigni Cert.).)

¹⁴⁵ (Rigler Dep. 122:12-14.)

¹⁴⁶ (Longo 4/17/19 *Weirick* Dep. 111:5-7, 124:17-20.)

There are numerous examples like this where Drs. Longo and Rigler's measurement falls outside their own stated ranges.¹⁴⁷ The only explanation is that they already decided they were going to call the mineral tremolite or anthophyllite and ran these post-hoc SAED "verifications" afterward. *See In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007) (excluding expert who "reache[d] his opinion by first identifying his conclusion" and then looked only at evidence that "support[ed] his conclusion[,] . . . ignoring the great weight of the evidence that contradicts his conclusion").

That appears to be what happened. On November 14, 2018, Drs. Longo and Rigler produced their first MDL report without any quantitative data from their SAED analysis, despite having concluded that their SAED analysis confirmed "tremolite" and "anthophyllite."¹⁴⁸ This made their conclusions completely unverifiable.

Drs. Longo and Rigler eventually produced additional data with what they called "Diffraction Verifications," which purport to confirm the SAED analysis in

¹⁴⁷ (Diffraction Verification M68503-001 at 7 (calculated spacing, 1.28 Å, falls outside of the range for all amphiboles listed); *id.* at 10, 35, 58 (same); Diffraction Verification M69757-005 at 23, 28 (same) (attached as Ex. A29 to Tersigni Cert.); Diffraction Verification M69042-002 at 12, 15, 16, 19, 20, 22 (same) (attached as Ex. A28 to Tersigni Cert.); *see also* Dyar Rep. at 37-38.)

¹⁴⁸ (*See, e.g.*, Longo Rep. at 126, 828.)

the November 14, 2018 report.¹⁴⁹ Both Dr. Longo and Dr. Rigler testified that this “verification” was done *after* the analysts made their judgment call on what mineral they were seeing under SAED.¹⁵⁰ Dr. Rigler even admitted that in many instances the analysts “verify that it is, in fact, whatever it was called before” the verification.¹⁵¹

Such post hoc testing is inherently suspect in the laboratory as well as in the courtroom – an expert’s commitment to his prior expressed findings will necessarily inject bias into later attempts to “verify” his prior results. *Cf., e.g., Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 405, 452 (D.N.J. 2009) (Wolfson, J.) (agreeing that “post-hoc analysis violates the rules and

¹⁴⁹ (See, e.g., Diffraction Verification M68503-001 at 5.)

¹⁵⁰ (See, e.g., *id.* at 5 (“Date Verified 1/31/2019”); Longo Dep. 182:16-19 (“Q. Okay. For many of the SAED patterns that have been produced in this case, the verification came after your November report; correct? A. That’s correct.”); Rigler Dep. 117:8-117:12 (similar).)

¹⁵¹ (Rigler Dep. 117:1-2.) Dr. Longo does not appear to even know how the SAED analysis was conducted. In his MDL deposition, on February 5, 2019, Dr. Longo testified of the software: “CrystalMaker? We have used it in the past, but we don’t use it for this analysis” (Longo Dep. 140:10-12), and “it’s not required for what we do” (*id.* 139:24-25). But at a deposition later, on April 17, 2019, he testified “we run CrystalMaker” which did all the measurements. (Longo 4/17/19 *Weirick* Dep. 120:3.) If *this* version of the story were true, Dr. Longo could have inputted the SAED pattern into CrystalMaker and “[j]out the other end [could] pop, the identification, this is tremolite.” (Longo Dep. 140:2:46.) But even under the version of their testimony where they used the software, Drs. Longo and Rigler did not do that. The software did not make the “decision on what amphibole it is.” (Longo 4/17/19 *Weirick* Dep. 101:6-8.) Dr. Longo agrees “[t]hat’s an analyst making that decision.” (*Id.* 101:12-13.)

underlying rationale for performing scientific analysis in a prospective, unbiased manner and that such testimony based on flawed methodology and flawed assumptions should be excluded”) (citation omitted). This is not a new approach for Dr. Longo. In *Lamar County Asbestos Litigation*, the court explained that he “started with the assumption that persons had been exposed to airborne asbestos fibers” from the defendant and then “selected methods to achieve the desired results stated in the MAS reports.”¹⁵² “This is not permitted” – there and here as well.¹⁵³

Drs. Longo and Rigler testified that they believed their SAED analysis appropriate because they also used EDXA. As discussed below, their EDXA methodology is entirely unreliable as well. Combining two unreliable methodologies does not make them reliable, and indeed, Drs. Longo and Rigler do not cite any authority in support of this sleight of hand.

C. EDXA: Drs. Longo And Rigler’s Opinions Should Be Excluded Because They Are Unreliable And Deliberately Designed To Be Unverifiable.

A proper EDXA analysis requires the evaluation of numerical data. Drs. Longo and Rigler ignored those data and omitted them from their reports in favor of a subjective and unreliable “eyeball” of a graphical image.

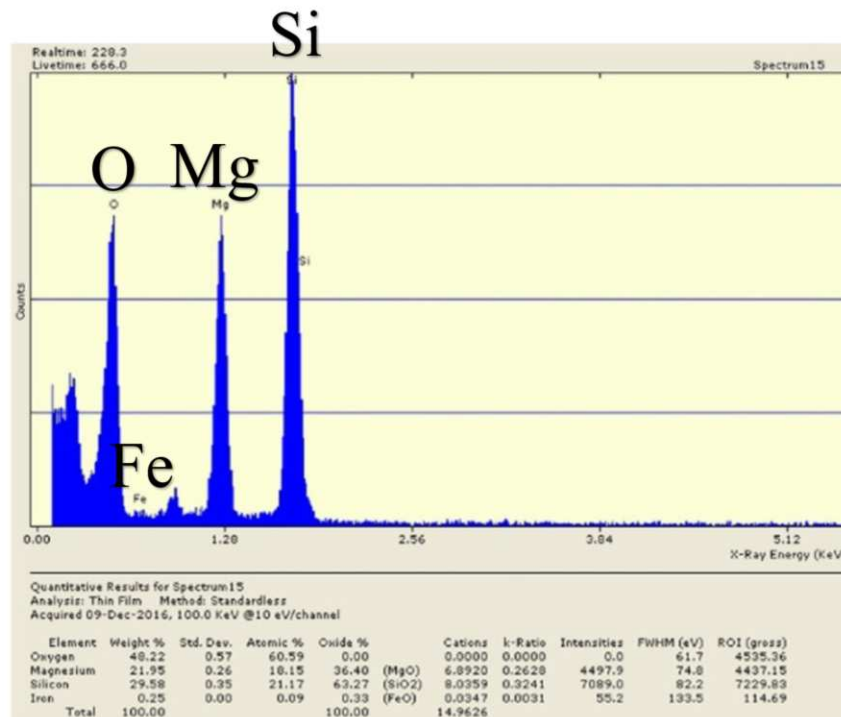
¹⁵² *In re Lamar Cty.* Order at 5.

¹⁵³ *Id.*

1. **Background: EDXA provides information about chemical composition.**

TEM can be used for EDXA, also called EDS.¹⁵⁴ An EDXA analysis produces information about the chemical composition of the particle, i.e., what elements are present in what proportions.¹⁵⁵ This in turn can help determine the mineral type (i.e., is it tremolite).

An EDXA graph contains peaks, each of which arises from individual elements.¹⁵⁶ Here is an image of part of an EDS graph, with the element symbols enlarged:



¹⁵⁴ (Longo Dep. 58:24-59:5 (EDXA and EDS refer to the same technique).)

¹⁵⁵ (Dyar Rep. at 15; Longo Dep. 70:3-6.)

¹⁵⁶ (Dyar Rep. at 15.)

Figure 9: EDXA graph with element symbols enlarged (adapted from Dyar Rep. at 22)

The numerical data underneath the graph provide information regarding each peak, such as its height and area, which can be used to determine the amount of each mineral present. Those data are critical because many minerals have very similar chemical compositions and this technique has a meaningful error rate.¹⁵⁷ Even under the best of circumstances, the error bars for EDXA are 5% or greater.¹⁵⁸ There are a number of factors that can interfere with the peaks actually being proportional to the amounts of the elements present.¹⁵⁹ As one court explained, “EDS is semiquantitative at best because asbestos has a varying elemental composition and other variables can affect the results.” *Hanson*, 353 F. Supp. 3d at 1281. An analyst needs the benefit of the data through which the computer corrects for complicating factors such as interactions between the minerals.¹⁶⁰

One way scientists try to determine chemical composition from an EDXA graph is to compare the proportions of silicon to the other minerals by measuring

¹⁵⁷ (See, e.g., *id.* at 17 (citing Newbury & Ritchie, *Performing elemental microanalysis with high accuracy and high precision by scanning electron microscopy*, J. Mater. Sci. 5-17 (2015)).)

¹⁵⁸ (*Id.*) See also Brydson 2014 at 13.

¹⁵⁹ (Dyar Rep. at 16 (referring to Longo Dep. 77:17-78:6, 101:8-13).) See also Yamate 1984 at 39.

¹⁶⁰ (Dyar Rep. at 22-23.)

the height or area of each peak.¹⁶¹ But because of the 5% or greater error rate, many minerals can look identical under EDXA. As just an example, readings for anthophyllite and talc can be indistinguishable.¹⁶² Other examples are graphically represented here, with the black bars representing the error rate inherent in EDXA:

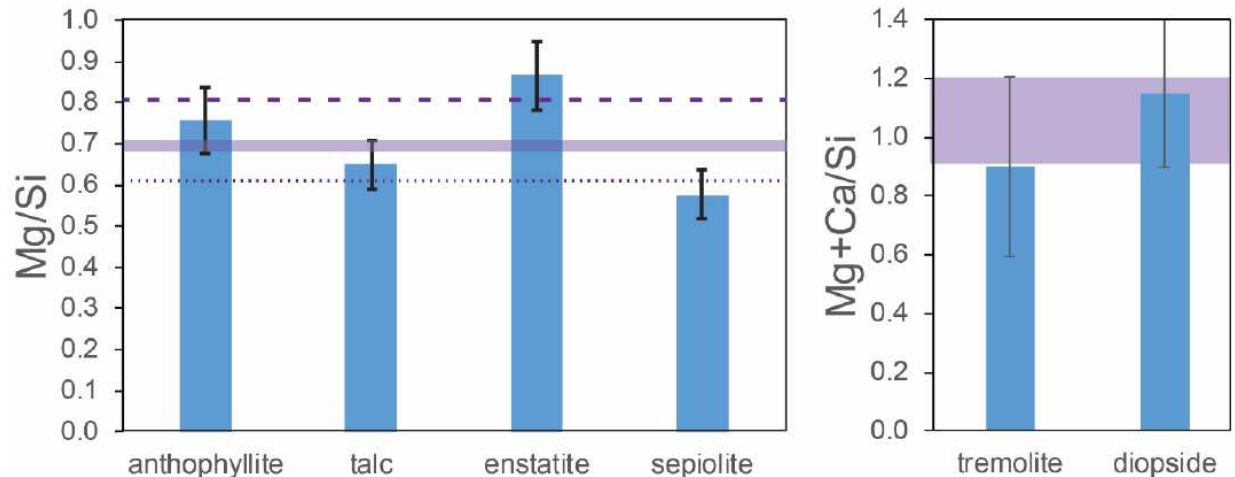


Figure 10: Graphs showing ratios of the weight percentage of magnesium to silicon displaying 5% error bars (Dyar Rep. at 18)

As Dr. Rigler admits, even an analyst using EDXA properly cannot “distinguish anthophyllite from talc using EDXA alone” or “distinguish anthophyllite from cummingtonite with EDXA alone.”¹⁶³

¹⁶¹ (*Id.* at 17; *see also* Yamate 1984 at 39; Longo Dep. 78:7-16, 80:3-4 (explaining that, for his EDXA analysis, he compares silicon peaks to other mineral peaks).)

¹⁶² (Dyar Rep. at 16, 18.)

¹⁶³ (Rigler Dep. 54:10-16.)

2. **Drs. Longo and Rigler omit from their report the critical data that are necessary in favor of “eyeballing” graphs.**

Because the peak areas may not be precisely proportional to the proportions of the elements and can be 5% off in either direction, the numerical data that go along with the graph are critical. As Dr. Rigler himself explained, it is necessary if one is “[t]rying to understand the composition of these materials” because it “is part of [the] info to try to figure out what you’re working with.”¹⁶⁴ That is precisely what Drs. Longo and Rigler claim they are attempting to do: figure out what the mineral is. Yet they not only ignored those data entirely, they omitted them from their reports.

This is a representative example of an EDXA graph from Drs. Longo and Rigler’s report, with the missing data circled in red:¹⁶⁵

¹⁶⁴ (*Id.* 61:2-6.)

¹⁶⁵ (Longo Dep. Ex. 12 (attached as Ex. B49 to Tersigni Cert.).)

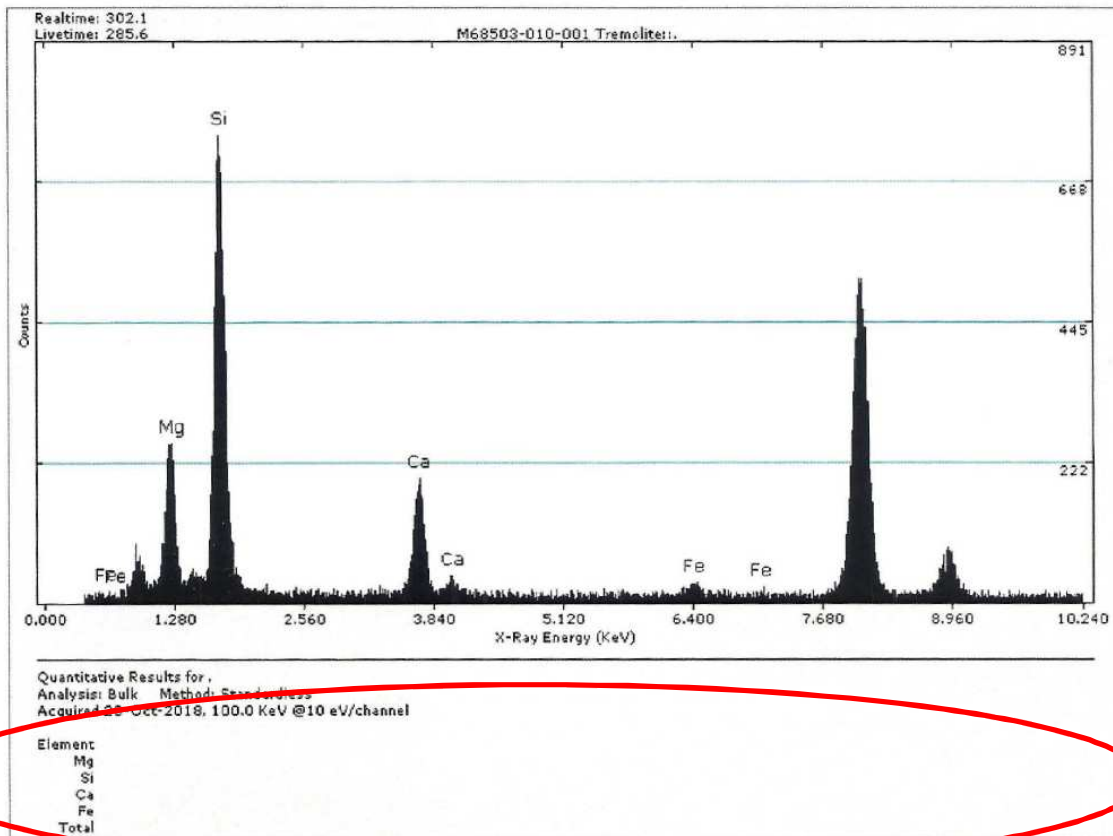


Figure 11: EDXA graph from Longo Report showing missing data

Notably, the critical numerical data at the bottom of the graph are not there. The same is true of every single EDXA graph in the report. Their software is perfectly capable of “generat[ing] information that fills in” those data.¹⁶⁶ Indeed, the MAS EDXA machine may have saved those data they opted not to disclose in the report,¹⁶⁷ but they have not been produced despite express requests.¹⁶⁸

¹⁶⁶ (Rigler Dep. 56:5-7; *see also* Longo Dep. 81:23-82:1 (“[T]here’s data that goes there that the software can generate.”); Longo Dep. 82:24-83:4 (“[T]hat data is just not something I’m relying on for my opinions in this case.”).)

¹⁶⁷ (Longo Dep. 82:8-10; Rigler Dep. 57:15-20.)

¹⁶⁸ (Longo Dep. 82:11-17; Rigler Dep. 58:9-11.)

Dr. Longo has previously been forced to admit that MAS redacted from another report pertinent information about the analytical sensitivity of his TEM analysis in connection with other talc litigation proceedings against defendants.¹⁶⁹

Instead of using the EDXA data, the analysts conducted their evaluation by “just visually confirming” it is close to what they expect the tremolite or anthophyllite graph to look like.¹⁷⁰ In other words, they are eyeballing it. Dr. Longo “doubt[s]” his analysts are even “looking at a known reference” when they see a graph they believe is tremolite or anthophyllite.¹⁷¹ There is no methodology at all other than “that looks like tremolite.”¹⁷²

Worse, without those data, Dr. Rigler agrees that the EDXA graph depicted above could “correspond to a number of other minerals.”¹⁷³ But the analysts “did not look at a textbook or peer-reviewed literature to determine what this ED[X]A

¹⁶⁹ (See Trial Tr. Vol. 7 1295:22-1296:19, *Ingham v. Johnson & Johnson*, No. 1522-CC10417-01 (Mo. Cir. Ct. June 8, 2018) (attached as Ex. E27 to Tersigni Cert.) (“Q. Those two things I just – you just agreed with me were important, analytical sensitivity, detection limit, those are the things that were whited out routinely in your report with a white box over them before they were sent to us Correct? A. Before they were sent to everybody, yes, it was – there was an edit on it . . . yes, that happened.”).)

¹⁷⁰ (Longo Dep. 81:10.)

¹⁷¹ (*Id.* 69:2-7.)

¹⁷² (*Id.* 123:20-22.) Dr. Longo testified that MAS has reference standards. (*Id.* 68:19-69:12, *esp.* 69:8 (“We have references . . .”).) But, if indeed they exist, he did not disclose them in his report and the PSC decided not to produce them.

¹⁷³ (Rigler Dep. 66:5-9.)

pattern could also correspond to other than what [Dr. Longo] believe[d] to be tremolite.”¹⁷⁴ They were paid to find tremolite or anthophyllite; thus, if they saw something that was visually close, that was good enough. And it is impossible to confirm their findings without the underlying data Drs. Longo and Rigler omitted.¹⁷⁵

3. Drs. Longo and Rigler’s EDXA methodology cannot survive Daubert.

Drs. Longo and Rigler’s approach is unreliable and fails *Daubert* for several interconnected reasons.

First, their subjective and error-prone approach of “eyeballing” EDXA charts to approximate particles’ chemical composition – instead of relying on available, quantifiable data – is inherently unreliable. In one case, a court excluded a handwriting expert because he did “little more than subjectively eyeball the various signatures and reach a bottom-line conclusion” and did “not describe any method for comparing handwriting, let alone whether this methodology has been tested or subject to peer review, there are any standards controlling this methodology, there are any know[n] error rates, or his handwriting comparison methods are generally accepted in the scientific community.” *United States v. Schultz*, No. 14-cr-467-3, 2016 WL 7409911, at *3 (N.D. Ill. Dec. 22, 2016).

¹⁷⁴ (Longo Dep. 128:5-9.)

¹⁷⁵ (Dyar Rep. at 23-24.)

The same is true of Drs. Longo and Rigler’s analysis, just with a chemical signature rather than a handwritten one. They simply eyeball the graphs, often without comparison to *anything*. And they *never* attempted to compare them to graphs for minerals other than anthophyllite and tremolite. Their report provides no authority for that being an acceptable methodology. That is unsurprising considering it is results-oriented and unreliable. Courts exclude this kind of “eyeballing” approach in a wide variety of contexts.¹⁷⁶

Second, the “eyeball” methodology is particularly egregious here, where the raw data *could have been* analyzed, or at least provided, to allow for an objective basis to test Drs. Longo and Rigler’s analysis. They simply opted not to look at those data, much less include them in their report.

¹⁷⁶ *United States v. Montgomery*, 635 F.3d 1074, 1093 (8th Cir. 2011) (affirming exclusion of expert’s opinion that someone’s gray matter appeared low “[b]ased on his ‘eyeball’ comparison”); *Cooper v. Brown*, 510 F.3d 870, 933 (9th Cir. 2007) (stating that expert’s offer to “eyeball” the volume of blood in a stain was “not acceptable to the Court” for “obvious reasons”); *Rogers v. Raymark Indus., Inc.*, 922 F.2d 1426, 1431 (9th Cir. 1991) (affirming exclusion of “‘eyeball’ comparison” of dust levels in two different plants under Rule 403 because it was not “reliable or useful”); *Disabled in Action*, 360 F. Supp. 3d at 244 (excluding expert who eschewed “provid[ing] exact measurements” of building features for ADA compliance in favor of an informal and unreliable “‘eye test’”); *Laux v. Mentor Worldwide, LLC*, 295 F. Supp. 3d 1094, 1101 (C.D. Cal. 2017) (excluding expert witness who “eyeball[ed]” valves to determine they were defective), *appeal filed*; *In re TMI Litig. Cases Consol. II*, 911 F. Supp. 775, 795-96 (M.D. Pa. 1996) (limiting expert’s testimony because, among other issues, his “failure to consider primary data in combination with his use of speculation, assumptions and ‘eyeballing’ of figures, expose[d] [the expert’s] methodology to a potentially high rate of error”).

In *Hanson*, the court excluded the testimony of an expert who purported to test talc samples for asbestos in part because he failed to record and produce data essential to verifying his results. 353 F. Supp. 3d at 1284-85. By omitting the data, the expert “ensured no other analyst could replicate his work and test his findings, as he underst[ood] having explained testing talc powder for asbestos is ‘like looking for a needle in a haystack.’” *Id.* at 1284. Omitting those data foreclosed the possibility that a “debate could have occurred on a level playing field with all material facts available to everyone as contemplated by *Daubert* and its progeny.” *Id.* at 1285. The Court concluded the omission of the data was “sufficient by itself to exclude” plaintiffs’ expert. *Id.*; cf. *Olson v. Mont. Rail Link, Inc.*, 227 F.R.D. 550, 553 (D. Mont. 2005) (issuing sanction under Rule 37 to preclude expert from relying on “any opinion or evidence based on undisclosed data or testing”).

Finally, the reason the omission of data is so important is because “[d]ocumentation is necessary to test a hypothesis” and “reproducibility is the *sine qua non* of ‘science.’” *Hebshie*, 754 F. Supp. 2d at 125. Under *Daubert*, “[s]omeone else using the same data and methods must be able to replicate the result.” *Zenith Elecs. Corp.*, 395 F.3d at 419. Indeed, Dr. Longo refused to answer when repeatedly asked whether an experienced third-party EDXA scientist would agree that one of the EDXA graphs he testified “look[ed] like tremolite” in fact

depicted tremolite.¹⁷⁷ That refusal is an admission that his conclusions are not reproducible and not objective.

Without the underlying data or even the graphs Drs. Longo and Rigler use as a basis of comparison, all that remains is inadmissible *ipse dixit*. The only basis to conclude that the graphs represent tremolite or anthophyllite is because Drs. Longo and Rigler say so. It is “supported merely by [their] personal assurance that they found asbestos.” *Hanson*, 353 F. Supp. 3d at 1285. All we have is “that looks like tremolite.”¹⁷⁸

D. PLM: Drs. Longo And Rigler’s Opinions Should Be Excluded Because They Use Methodologies That Do Not Produce Reliable Or Reproducible Results.

Dr. Longo has testified that Polarized Light Microscopy (“PLM”) is not the proper methodology for testing talc for asbestos, yet he did it anyway, following a protocol that states on its face that it is not designed for the alleged low concentrations at issue here. It is a protocol Dr. Longo only became aware of months earlier. Drs. Longo and Rigler sent their samples to another lab to test using that same protocol in order to demonstrate the reliability of their analysis. Their plan backfired. The other lab did not detect asbestos in *any* of the samples received from Drs. Longo and Rigler.

¹⁷⁷ (Longo Dep. 122:2-124:14.)

¹⁷⁸ (*Id.* 122:12.)

1. Background: PLM provides information on morphology and mineral type.

Separate from TEM, a MAS analyst also examined samples under a different type of microscope: through PLM. When examining a mineral under PLM, the mineral is placed in a series of special fluids, and when a certain kind of light is shined through the mineral onto a detector, it creates an image of the mineral's particles.¹⁷⁹ The color of the particle in each of the series of fluids can help determine what type of mineral it is.¹⁸⁰

Dr. Longo has *never* “personally analyzed a sample for the presence of asbestos using PLM.”¹⁸¹ As he put it: “I don’t do PLM analysis.”¹⁸² Dr. Rigler similarly admits, “I am not a PLM microscopist.”¹⁸³ Dr. Longo has also previously testified that “the PLM method is not appropriate to do an evaluation for these types of products” – i.e., talcum powder products.¹⁸⁴ He believes that “[t]he concentration is too low and you’re dealing with small fibrous structures and it’s

¹⁷⁹ (Dyar Rep. at 43-45.)

¹⁸⁰ (*Id.* at 45.)

¹⁸¹ (Dep. of William E. Longo, Ph.D. 85:18-20, *Young v. Johnson & Johnson*, No. 1522-CC09728-02 (Mo. Cir. Ct. Jan. 25, 2019) (attached as Ex. E12 to Tersigni Cert.).)

¹⁸² (*Id.* 86:5-6.)

¹⁸³ (Rigler Dep. 20:1.)

¹⁸⁴ (Tr. 2921:25-28, *Weirick v. Brenntag N. Am.*, No. BC656425 (Cal. Super. Ct. Aug. 24, 2018) (attached as Ex. E31 to Tersigni Cert.).)

going to be beyond the resolution of the PLM.”¹⁸⁵ He said when trying to determine whether asbestos is present in talc, “TEM is the only method to determine that.”¹⁸⁶

2. Drs. Longo and Rigler applied the wrong methodology, using reference standards they decided not to produce.

Though Dr. Longo believes PLM is not the “appropriate” methodology in this context, and neither he nor Dr. Rigler conducts PLM analysis, they went ahead and did so anyway. Drs. Longo and Rigler claim to follow the ISO 22262-1 methodology for PLM.¹⁸⁷

ISO 22262-1 can only be used for rough estimates, as the method itself states that “it is recognized that the accuracy and reproducibility of” its quantifications of asbestos content “is very limited.”¹⁸⁸ Accordingly, ISO 22262-1 states that when the asbestos concentration found is between 0% and 5% and “it is necessary to make critical decisions on the basis of the results” (including a result of “non-detected”) then ISO 22262-2 should be used.¹⁸⁹

¹⁸⁵ (Dep. of William E. Longo, Ph.D. 283:5-7, *Weirick v. Brenntag N. Am.*, No. BC656425 (Cal. Super. Ct. Apr. 17, 2018) (attached as Ex. E9 to Tersigni Cert.).)

¹⁸⁶ (Dep. of William E. Longo, Ph.D. 203:12-13, *Wittman v. Brenntag N. Am.*, No. BC 646439 (Cal. Super. Ct. Nov. 20, 2017) (attached as Ex. E11 to Tersigni Cert.).)

¹⁸⁷ (Longo Dep. 267:12-268:1.)

¹⁸⁸ ISO 22262-1 at vi.

¹⁸⁹ *Id.* at 35 n.1.

When analyzing under the more powerful TEM microscope, Drs. Longo and Rigler claimed to detect asbestos at concentrations ranging from .0092% on the high end to .0000033% (3.3 millionths of a percent) on the low end. Despite Dr. Longo's earlier claim that the concentrations are too low for PLM to be reliable, he did not use ISO 22262-2 which is designed specifically for lower concentrations. Once again, Drs. Longo and Rigler intentionally selected methodologies that are not appropriate for the context.

Moreover, the MAS PLM analysts reached these concentration conclusions using internal MAS "weight percentage standards."¹⁹⁰ Dr. Longo did not disclose these in his report, and the PSC did not produce them.¹⁹¹ *Cf. Bracco*, 627 F. Supp. 2d at 405, 446 (striking portion of expert's survey based on web-page recreations that "were never produced" but were "critical to obtaining accurate and reliable survey results").

3. Drs. Longo and Rigler's results are inconsistent.

As discussed above regarding visual TEM, Drs. Longo and Rigler took it upon themselves to create a test of their own consistency and reliability by having four analysts examine the same TEM grid openings. They failed their own test

¹⁹⁰ (2d Suppl. Longo Rep. at 10; Longo Dep. 269:24-270:16.)

¹⁹¹ (Longo Dep. 270:16; *see also* Email Exchange between Susan Sharko and P. Leigh O'Dell, Feb.-Mar. 2019 (attached as Ex. I2 to Tersigni Cert.) (including requests for these documents on 2/15/19, 3/14/19 and 3/26/19).)

because the analysts came to wildly inconsistent determinations about whether a structure was a bundle or a fiber.

For PLM, Drs. Longo and Rigler *again* took it upon themselves to test their own consistency and reliability. And once again they failed their own test. They arranged to have Lee Poye of J³ Resources, a separate lab, analyze 37 of the samples. They did this because they “wanted to see the difference between the two labs that used that method.”¹⁹² Dr. Longo thus asked Poye to “analyze [the samples] by the ISO 22262-1 protocol for PLM,” the exact same method Drs. Longo and Rigler used on those same samples.¹⁹³ Dr. Longo said of Mr. Poye: “I’ve known Lee for a long time. He’s a good lab.”¹⁹⁴

Of the 37 samples, Drs. Longo and Rigler detected asbestos in eight following the ISO 22262-1 protocol. Mr. Poye did not detect asbestos in *any* of the 37.¹⁹⁵ In other words, he could not reproduce Drs. Longo and Rigler’s results.

Drs. Longo and Rigler also applied another PLM methodology in addition to ISO 22262-1 that they call the “Blount PLM” – a method that has never been approved by any government agency. It involves an additional preparation step

¹⁹² (Dep. of William E. Longo, Ph.D. 91:13-14, *Rimondi v. BASF Catalysts LLC*, No. MID-L-2912-17 (N.J. Super. Ct. Law Div. Jan. 7, 2019) (attached as Ex. E6 to Tersigni Cert.).)

¹⁹³ (*Id.* 88:24-25.)

¹⁹⁴ (Longo 3/29/18 *Anderson* Dep. 67:13-14.)

¹⁹⁵ (2d Suppl. Longo Rep. at 49-51).

before the sample is analyzed through PLM.¹⁹⁶ The idea is to examine the portion of the sample where the asbestos is concentrated to make it easier to detect.¹⁹⁷ Yet, there were only three instances where Drs. Longo and Rigler detected asbestos by Blount PLM where they did not by ISO PLM. But there were as many instances where they detected asbestos by ISO PLM where they did not by Blount PLM.

Below is a chart showing the results of the 37 samples that Mr. Poye tested by the ISO PLM method as compared to MAS's PLM work:¹⁹⁸

Sample No.	Longo/Rigler ISO PLM	Poye ISO PLM	Longo/Rigler Blount PLM
M68503-010	No	No	Detect
M68503-009	No	No	Detect
M68503-024	No	No	No
M68503-004	Detect	No	No
M68503-014	No	No	No
M68503-011	No	No	No
M68503-027	No	No	No
M68503-019	No	No	No
M68503-038	No	No	No
M68503-026	Detect	No	Detect
M68503-005	No	No	No
M68503-029	No	No	No
M68503-021	No	No	No
M68503-023	Detect	No	Detect
M68503-028	No	No	Detect
02D	[Not analyzed]	No	No
M68503-046	No	No	No
M68503-042	Detect	No	Detect

¹⁹⁶ The talc is placed in a “heavy liquid” solution with the goal of causing talc particles (which are less dense than the solution) to rise and non-talc particles such as tremolite and some anthophyllite to sink. (*Id.* at 6.)

¹⁹⁷ (*Id.*)

¹⁹⁸ (*Id.* at 33-51.)

M68503-057	Detect	No	No
M68503-020	Detect	No	Detect
07D	[Not analyzed]	No	Detect
15D	[Not analyzed]	No	Detect
50D	[Not analyzed]	No	Detect
M68503-059	Detect	No	Detect
10D	[Not analyzed]	No	Detect
38D	[Not analyzed]	No	Detect
63D	[Not analyzed]	No	Detect
52D	[Not analyzed]	No	Detect
65D	[Not analyzed]	No	Detect
37D	[Not analyzed]	No	Detect
45D	[Not analyzed]	No	Detect
51D	[Not analyzed]	No	Detect
66D	[Not analyzed]	No	Detect
21D	[Not analyzed]	No	Detect
M68503-001	Detect	No	Detect
31F	[Not analyzed]	No	Detect
31G	[Not analyzed]	No	Detect

The same lack of replicability is true with another aspect of Drs. Longo and Rigler's PLM analysis. As with TEM, Dr. Longo has demonstrated that he cannot reliably differentiate between bundles and fibers when using PLM. At his deposition, Dr. Longo was presented with images of both asbestiform and non-asbestiform tremolite from a publication by the Bureau of Mines on identifying and characterizing amphibole minerals.¹⁹⁹ As Dr. Longo has described it when he has relied on this publication at trial, "The Campbell paper talks about how you define something that is asbestiform and non-asbestiform."²⁰⁰ It includes a number of asbestiform and nonasbestiform analogues of the same mineral alongside one

¹⁹⁹ Campbell 1977 at 42.

²⁰⁰ (Tr. 3275:5-7, *Allen v. Brenntag N. Am.*, No. DR180132 (Cal. Super. Ct. Oct. 17, 2018) (attached as Ex. E21 to Tersigni Cert.).)

another in a section aptly entitled “Comparison of Particulates From Known Serpentine and Amphibole Minerals and Their Asbestiform Varieties.”²⁰¹

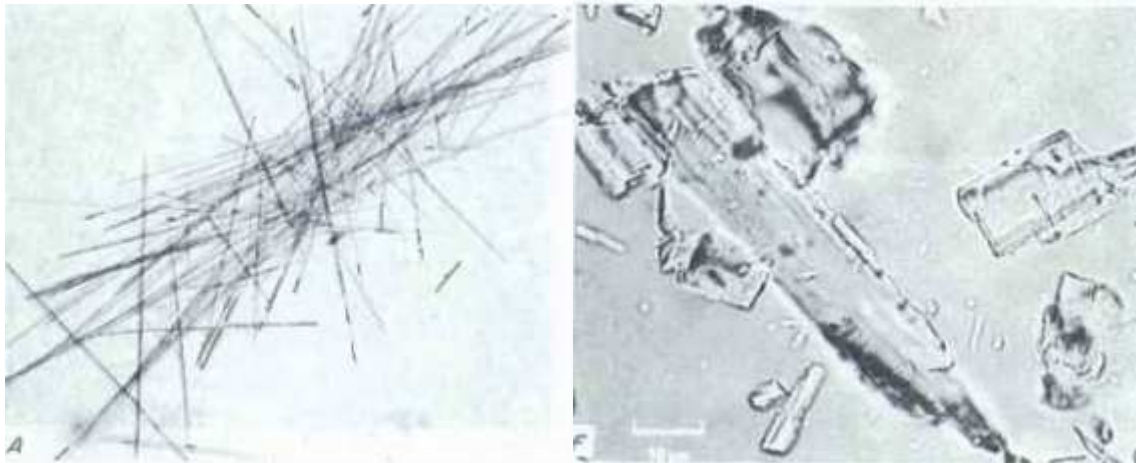


Figure 12: PLM images of tremolite asbestos and nonasbestiform tremolite (Campbell 1997 at 42; Longo Dep. Ex. 22).

These images were extracted and Dr. Longo was asked to characterize the minerals at his deposition. He correctly identified the image on the left stating: “looking at the photograph, I would state that that is a regulated asbestos size – asbestiform or not for these different photographs.”²⁰² He reached the right conclusion, but the gap in his methodology became clear once he was presented with the nonasbestiform image. Referring to the image on the right, he said:

So if it’s under an optical microscopy method and it meets the definition, it’s got parallel sides, it looks like it

²⁰¹ Campbell 1977 at 42.

²⁰² (Longo Dep. 248:6-8 (referring to Longo Dep. Ex. 22).)

has multiple fibers in the bundle, that by definition is asbestiform.²⁰³

He was wrong. The image on the right is a chunk of rock, not an asbestiform bundle. Just as Dr. Longo's analysts failed the TEM bundle test, he failed to accurately identify a bundle with PLM.

Inconsistent results are an indicator of unreliability. For example, *Paoli II* involved an expert who ran two different kinds of tests to attempt to detect a particular type of chemical. 35 F.3d at 777. The Third Circuit affirmed the exclusion of the expert where a "methodological problem" with the expert's analysis was that the two tests "produced inconsistent results." *Id.*; see also *In re Diet Drugs*, 2001 WL 454586, at *13 ("Dr. Bloor could not reproduce his own results when asked to re-score the slides using his own method.").

Drs. Longo and Rigler's analysis is similarly inconsistent. On their own accord they sent samples to another lab in an attempt to demonstrate the reliability of their findings. But that lab found *no* asbestos by PLM. Just like their bundle vs. fiber analysis, having made the choice to attempt to demonstrate repeatability, they have to live with the outcome of the test they set for themselves. It demonstrates that their analysis is not, in fact, repeatable. Drs. Longo and Rigler's PLM testing thus should be excluded.

²⁰³ (*Id.* 250:9-13.)

III. PLAINTIFFS HAVE NO SUPPORT FOR THE THEORY THAT THE LEVELS AND TYPES OF ASBESTOS ALLEGED TO BE PRESENT IN THE PRODUCTS CAUSE OVARIAN CANCER.

Thirteen of plaintiffs' experts seek to piggyback off of Drs. Longo and Rigler's testing and opine that the alleged asbestos in cosmetic talc causes ovarian cancer.²⁰⁴ These opinions are unreliable for several reasons.

As a threshold matter, "[t]he relationship between asbestos exposure and ovarian cancer is not . . . well understood," and scientists have stated that IARC's conclusion that asbestos can cause ovarian cancer was "premature."²⁰⁵ *See supra* Background § F. There are two reasons for this uncertainty. First, although some studies involving very high occupational exposure to asbestos did find an association with ovarian cancer, other studies that looked at environmental exposure did not. Second, scientists now believe that some of the incidences of

²⁰⁴ (*See, e.g.*, Expert Report of Ellen Blair Smith, M.D. at 8-9, Nov. 16, 2018 (attached as Ex. C16 to Tersigni Cert.); Expert Report of Arch Carson, M.D., Ph.D. ("Carson Rep.") at 5, Nov. 16, 2018 (attached as Ex. C9 to Tersigni Cert.); Expert Report of Daniel L. Clarke-Pearson ("Clarke-Pearson Rep.") at 5, Nov. 16, 2018 (attached as Ex. C14 to Tersigni Cert.); Expert Report of Sarah E. Kane, M.D. ("Kane Rep.") at 32-33, Nov. 15, 2018 (attached as Ex. C38 to Tersigni Cert.); Levy Rep. at 15-17; McTiernan Rep. at 56-59; Moorman Rep. 36-38; Expert Report of Laura M. Plunkett, Ph.D., D.A.B.T. ("Plunkett Rep.") at 22, 48-49, Nov. 16, 2018 (attached as Ex. C28 to Tersigni Cert.); Siemiatycki Rep. at 29-30; Expert Report of Sonal Singh, M.D., M.P.H. at 14-16, 19, 59-60, Nov. 16, 2018 (attached as Ex. C40 to Tersigni Cert.); Smith-Bindman Rep. at 5, 14-15; Expert Report of Judith Wolf, M.D. ("Wolf Rep.") at 9, Nov. 16, 2018 (attached as Ex. C23 to Tersigni Cert.); Expert Report of Judith Zelikoff, Ph.D. at 8, Nov. 16, 2018 (attached as Ex. C24 to Tersigni Cert.).)

²⁰⁵ Reid 2011 at 1287, 1294.

ovarian cancer reported in older studies involving occupational asbestos exposure may have actually been peritoneal mesothelioma that was misclassified as ovarian cancer because of poor diagnostic techniques.²⁰⁶ As Dr. Kurman explains, “there is a significant likelihood that some tumors observed in these occupational studies, which are quite dated, were misclassified due to misreporting on death certificates and lack of immunohistochemical analysis to adequately distinguish peritoneal mesothelioma from ovarian cancer.”²⁰⁷ As Dr. Reid noted, “even misclassification of 1 cancer may exert a large impact on the exposure effect” because the associations in the occupational studies were relatively modest.²⁰⁸

Even if the literature did demonstrate a real association between significant occupational exposure to certain asbestos minerals and ovarian cancer, plaintiffs’ experts’ causation opinions would still fail *Daubert* because: (1) the supposed exposure of women to asbestos in talc is minuscule, compared to the exposures at

²⁰⁶ *Id.* at 1293.

²⁰⁷ (Expert Report of Robert J. Kurman at 14, Feb. 25, 2019 (attached as Ex. C37 to Tersigni Cert.).)

²⁰⁸ Reid 2011 at 1293-94. (*See also* Dep. of Robert Kurman, M.D. 91:19-93:4, Apr. 2, 2019 (attached as Ex. B44 to Tersigni Cert.) (noting that the few studies relied upon for the proposition that there is a connection between asbestos exposure and ovarian cancer involve “massive exposures of asbestos in women who are occupationally exposed” and explaining that there is a “significant risk” that these studies involved “mesotheliomas that were misclassified” as ovarian cancer); Expert Report of Kevin Holcomb, M.D., F.A.C.O.G. at 6-7, Feb. 25, 2019 (attached as Ex. C27 to Tersigni Cert.) (similar).)

issue in the literature cited by plaintiffs' experts; (2) the literature on which they rely largely involved exposure to crocidolite asbestos – the most potent form of asbestos – and none of the studies involved tremolite or anthophyllite, the two asbestos minerals that Drs. Longo and Rigler claim to have found in the Products; and (3) plaintiffs' experts' "any exposure" opinions are speculative and inadmissible.

A. The Epidemiological Literature Does Not Support Any Association Between Asbestos And Ovarian Cancer At The Non-Occupational Exposure Levels Described By Drs. Longo And Rigler.

Courts applying *Daubert* have rejected causation opinions where the plaintiff's alleged exposure to asbestos or a different carcinogen was dissimilar from that of the subjects in the studies supposedly supporting the causal theory. *See, e.g., Schudel v. Gen. Elec. Co.*, 120 F.3d 991, 997 (9th Cir. 1997) (reversing admission of causation expert who relied on studies that "examined long-term exposure at relatively low chemical concentrations or short-term exposure at very high concentrations, rather than the short-term, moderate-level exposure sustained by [plaintiff]"), *abrogated on other grounds by Weisgram v. Marley Co.*, 528 U.S. 440 (2000); *Boyer v. Weyerhaeuser Co.*, No. 14-cv-286-wmc, 2016 WL 705233, at *14, *22, *23 (W.D. Wis. Feb. 19, 2016) (striking expert opinions that non-occupational exposure to asbestos caused lung cancer because plaintiffs' environmental exposure to defendant's asbestos was not comparable to the

occupational exposure involved in the study); *Mercer v. Rockwell Int'l Corp.*, 24 F. Supp. 2d 735, 752-53 (W.D. Ky. 1998) (jury could not rely on expert's opinion because no scientific study or research supported his opinion that chemical exposure at levels plaintiffs experienced increased risk of cancer); *Sutera v. Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 662-63 (D. Mass. 1997) (finding studies "simply do not demonstrate any scientific support for the proposition that [plaintiff]'s ingestion of benzene at low levels" caused leukemia because, among other things, they involved benzene exposure "***substantially greater in orders of magnitude***" and "***thousands of fold higher' than those that are at issue in this case***") (emphases added); *Tumlinson v. Advanced Micro Devices, Inc.*, 81 A.3d 1264, 1271 (Del. 2013) (affirming exclusion of expert who "failed to distinguish between the plaintiffs' differing work environments and how these environments may have impacted exposure levels").

This is such a case. Even if the Products did contain asbestos fibers at the highest levels alleged by Drs. Longo and Rigler, those concentrations are not remotely comparable to the prolonged, heavy occupational exposure levels in the studies on which plaintiffs rely.²⁰⁹ Of the MDL samples that Dr. Longo tested, for

²⁰⁹ See IARC 2012 Monograph at 256 (noting that the majority of studies regarding asbestos and ovarian cancer involved "heavy occupational exposure"); Reid 2011 at 1287 (noting that studies that have examined asbestos exposure and ovarian cancer are limited because of the small number of cases and the difficulties

example, the **highest** concentration of “asbestos” fibers identified “was around .0092 of a percent, or 9.2 thousandths of a percent” by weight.²¹⁰ Others were much lower; sample M69042-003, for example, was only .0000033% “asbestos” by weight and sample M69751-036 was only .00000022% “asbestos” by weight.²¹¹ Even assuming (contrary to all evidence) that these measurements are accurate and refer to **asbestiform** particles, they would correspond to incredibly low levels of airborne asbestos exposure.²¹² Using the highest concentration to illustrate, 50-year cumulative airborne asbestos fiber exposures would be: ***three times less than those associated with ambient, background exposure; at least 4,000 times below the lifetime asbestos concentration associated with OSHA’s permissible exposure limit; and at least 29,000 times below tremolite asbestos levels considered protective of mesothelioma.***²¹³ Because the studies on which

with diagnosis).

²¹⁰ (Longo Rimondi Tr. Vol. I 194:22-25.)

²¹¹ (See 2d Suppl. Longo Rep. at 33 tbl. 2; *id.* at 45 tbl. 5.)

²¹² (Moore Rep. at 52-56.) Dr. Moore, accepting Dr. Longo’s findings, calculated an airborne asbestos concentration of .001348 structures per cubic centimeter of air. (*Id.* at 46.) This is not far from Dr. Longo’s own calculations at a recent deposition, where he put the median estimated airborne asbestos concentration at .002 fibers per cubic centimeter of air. (Longo 4/17/19 *Weirick* Dep. 90:1-17.)

²¹³ “Ambient, background exposure” refers to the concept that individuals are exposed to some level of asbestos present in the air as a result of past mining of asbestos and the formerly common use of asbestos in buildings and products. *See generally* Abelman et al., *Historical Ambient Airborne Asbestos Concentrations*

plaintiffs rely involve “individuals whose circumstances were very different from those” here, they are “without evidentiary significance” and cannot support the opinions of plaintiffs’ experts. *Bostic v. Ga.-Pac. Corp.*, 439 S.W.3d 332, 358 (Tex. 2014) (citation omitted).

Moreover, studies involving non-occupational environmental exposure to asbestos **have not** found a statistically significant association between such exposures and ovarian cancer.²¹⁴ For this reason, too, a causal connection cannot be supported. *See, e.g., In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 456 (E.D. Pa. 2014) (rejecting expert’s opinion where expert relied “on trends in non-statistically significant data to draw conclusions . . . rather than on replicated statistically significant findings”); *Smith v. Ford Motor Co.*, No. 2:08-cv-630, 2013 WL 214378, at *4 (D. Utah Jan. 18, 2013) (causation studies contradicted expert because “all of these studies have shown no statistically significant difference”).²¹⁵

in the United States – An Analysis of Published and Unpublished Literature (1960s-2000s), 27(14) *Inhal. Toxicol.* 754 (2015) (attached as Ex. A1 to Tersigni Cert.).

²¹⁴ *See* IARC 2012 Monograph at 254-55 (citing Reid 2009 (SIR 1.18 (95% CI 0.45-1.91)); Reid 2008 (SMR 1.26 (95% CI 0.58-2.40)); Ferrante 2007 (1.42 SMR (95% CI 0.71-2.54))).

²¹⁵ Defendants anticipate that plaintiffs will challenge the importance of statistical significance, but for the reasons set forth in defendants’ general causation brief (*see* Mem. in Supp. of Mot. to Exclude Pls.’ Gen. Causation Ops. at

In sum, plaintiffs’ experts cannot point to any “scientific peer-reviewed epidemiological studies” linking asbestos exposure comparable to that at issue here with ovarian cancer. *See Sutura*, 986 F. Supp. at 662. Because plaintiffs’ experts “simply do not demonstrate any scientific support for the proposition that” exposure to “low levels” of asbestos causes ovarian cancer, the Court should reject their “novel scientific theory.” *See id.*; *Lofgren v. Motorola, Inc.*, No. CV 93-05521, 1998 WL 299925, at *1, *19 (Ariz. Super. Ct. June 1, 1998).

B. The Epidemiological Literature Is Heavily Focused On Crocidolite, The Most Potent Form Of Asbestos, Which No One Claims Is Found In Talc.

Plaintiffs’ experts’ causation opinions are also unreliable because the ovarian cancer studies they cite primarily involve exposure to large amounts of *crocidolite* asbestos, which is not alleged to be a contaminant of talc.

Courts have recognized in asbestos cases that “any epidemiological studies plaintiffs use to show the link between [a plaintiff’s] exposure to the defendants’ products and his mesothelioma must,” among other things, “involve the same type of asbestos fibers present in defendants’ products.” *E.g., In re Asbestos Prods. Liab. Litig. (No. VI)*, No. 11-60070, 2012 WL 760739, at *8 (E.D. Pa. Feb. 17,

61-66), plaintiffs’ arguments lack scientific foundation. Moreover, there are no studies that have ever reported an ovarian cancer risk at the asbestos exposure levels alleged here, rendering the question of statistical significance moot in this context.

2012), *report and recommendation adopted*, 2012 WL 775681 (E.D. Pa. Mar. 9, 2012). This is because it is “well-known that small differences in chemicals and molecular structure can and do result in substantial differences in toxicity and carcinogenicity.” *Lofgren*, 1998 WL 299925, at *23.

In asserting that asbestos can cause ovarian cancer, plaintiffs’ experts repeatedly cite IARC’s causation conclusion, which was based on five studies involving heavy occupational exposure predominantly to crocidolite asbestos.²¹⁶ But those same studies and others make clear that crocidolite is uniquely toxic among the asbestos minerals.²¹⁷ As Dr. Mossman explains in her report, one study reported that “the relative potency of chrysotile:amosite:crocidolite was 1:83:376-

²¹⁶ (See, e.g., Carson Rep. at 5 (citing IARC as support for his statement that asbestos can cause ovarian cancer); Moorman Rep. at 35 (“IARC has stated that ‘a causal association between exposure to asbestos and cancer of the ovary was clearly established,’ based on strongly positive cohort mortality studies of women with occupational exposure to asbestos as well as studies of women with environmental exposure to asbestos.”).)

²¹⁷ See Acheson et al., *Mortality of Two Groups of Women Who Manufactured Gas Masks from Chrysotile and Crocidolite Asbestos: A 40-Year Follow-Up*, 39 Br J Ind Med 344, 347 (1982) (attached as Ex. A2 to Tersigni Cert.) (study reporting a “significant excess of mortality from lung and ovarian cancer” in workers exposed to crocidolite, but not workers exposed to chrysotile; “The probable explanation for the difference . . . lies in the different nature of the exposures in the two factories”); Reid 2011 at 1269-70 & tbl. 1, 1291 (setting forth these and other results indicating crocidolite is more toxic; separately observing that crocidolite is “the most mesotheliogenic of the asbestos fibers”); IARC 2012 Monograph at 242, 254-55 (concluding that there is a causal association based primarily on studies involving crocidolite); Camargo 2011 at 1215 (“Cohorts predominately exposed to crocidolite or mixed [i.e., crocidolite and chrysotile] asbestos showed larger SMRs than did those exposed only to chrysotile asbestos.”).

fold.”²¹⁸ But crocidolite is not alleged to be present in the Products,²¹⁹ and there are no studies finding that exposure to the types of “asbestos” at issue here is associated with an increased risk of ovarian cancer.²²⁰

For this reason, too, plaintiffs’ experts’ opinions that asbestos in talc can cause ovarian cancer should be excluded. *See Lofgren*, 1998 WL 299925, at *23.

C. Plaintiffs’ Experts’ Effort To Overcome The Mismatch Between Their Findings And The Literature By Resorting To “Any Exposure” Theories Of Causation Is Unscientific And Unreliable.

Finally, several of plaintiffs’ experts attempt to elide the fact that no scientific studies support their position on causation by asserting that exposure to even a single fiber of any type of asbestos can cause ovarian cancer. These opinions are unreliable and inadmissible.

Courts have repeatedly rejected opinions to the effect that any and every exposure to asbestos, no matter how trivial, is capable of causing disease as unreliable.²²¹ These sorts of opinions fail *Daubert*, as numerous courts have held,

²¹⁸ (Expert Report of Brooke Taylor Mossman, M.S., Ph.D. (“Mossman Rep.”) at 14, Feb. 25, 2019 (attached as Ex. C11 to Tersigni Cert.).)

²¹⁹ (*See generally* 2d Suppl. Longo Rep. (failing to identify any crocidolite); *see also* Am. Cook Rep. (same); Krekeler Rep. (same).)

²²⁰ *See, e.g.*, Reid 2011 at 1269-70 & tbl. 1 (table showing that the studies reporting an association between asbestos and ovarian cancer have looked at exposure to crocidolite and chrysotile asbestos).

²²¹ (*See, e.g.*, Dep. of Judith Zelikoff, Ph.D. 265:9-11, Jan. 21, 2019 (attached as Ex. B31 to Tersigni Cert.) (testifying that “one fiber of asbestos could start the

because basic tenets of toxicology demand that exposure assessments take account of dose. *See, e.g., Anderson v. Ford Motor Co.*, No. 2:06-CV-741 TS, 2013 WL 3179497, at *5 (D. Utah June 24, 2013) (concluding that the “every exposure counts” theory “is based on their lack of information sufficient to show the level of exposure which does not create a risk of mesothelioma. This is not reliable enough evidence for the Court to allow it in under the standards of *Daubert* and Rule 702”); *see also Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 679-80 (6th Cir. 2011) (“[I]t is well-settled that the mere existence of a toxin in the environment is insufficient to establish causation without proof that the level of exposure could cause the plaintiff’s symptoms.”); *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1242 (11th Cir. 2005) (stating that causation “requires not simply proof of exposure to the substance, but proof of enough exposure to cause the plaintiff’s specific illness”); *In re W.R. Grace & Co.*, 355 B.R. 462, 476 (D. Del. 2006) (“The use of the no safe level or linear ‘no threshold’ model for showing unreasonable risk ‘flies in the face of the toxicological law of dose-response, that is, that ‘the dose makes the poison,’ which refers to the general tendency for a greater dose of a toxin to cause greater severity of responses in individuals, as well as greater frequency of response in populations.’”) (citing Federal Judicial Center, *Reference Manual on*

biological process” to cause ovarian cancer); Plunkett Rep. at 21; Moorman Rep. at 35; Wolf Rep. at 15; Kane Rep. at 29; Clarke-Pearson Rep. at 9.)

Scientific Evidence 475 (2d ed. 2000)); *Burgad v. Jack L. Marcus, Inc.*, 345 F. Supp. 2d 1037, 1042 (D.N.D. 2004) (“The mere presence of chemicals . . . is not sufficient, by itself, to establish liability or causation in a products liability action.”).²²²

Evidence of dose is particularly critical to causation opinions based on asbestos exposure because *certain levels of asbestos exposure do not pose a health risk*. See *In re W.R. Grace*, 355 B.R. at 476 (explaining that “some levels of exposure [to asbestos] pose no risk,” and that “individuals in urban areas live with low levels of asbestos exposure their entire lives without risking their health”); see also *In re Asbestos*, 2012 WL 760739, at *7. As one court observed, “it is not a valid assertion that because high dose exposure to asbestos is bad for you, then low dose exposure to asbestos is, in fact, bad for you.” *In re Toxic Substance Cases*, No. 03-319, 2006 WL 2404008, at *7 (Pa. Ct. Com. Pl. Aug. 17, 2006). To the contrary, “the poison is in the dose.” *Id.* The opinions proffered by Drs. Zelikoff, Plunkett, Moorman, Wolf, Kane and Clarke-Pearson that any amount of exposure to asbestos would be sufficient to cause ovarian cancer are the exact kind

²²² See also Silbergeld, *The Role of Toxicology in Causation: A Scientific Perspective*, 1 Courts. Health Sci. & L. 374, 378 (1991) (attached as Ex. A133 to Tersigni Cert.) (“‘The dose makes the poison’; this implies that all chemical agents are intrinsically hazardous—whether they cause harm is only a question of dose. Even water, if consumed in large quantities, can be toxic.”).

of “inadmissible speculation that is devoid of responsible scientific support.”

Smith, 2013 WL 214378, at *2.

For similar reasons, Drs. Longo and Rigler’s unsupported conclusion that consumers using the Products “would have, more likely than not, been exposed to significant airborne levels of both regulated amphibole asbestos and fibrous (asbestiform) talc”²²³ should be excluded as mere *ipse dixit* that cannot support causation. “Significant” is not a defined threshold – indeed, Dr. Longo has previously conceded that this is not a statement “about the health effects of that level”²²⁴ – and the objective metrics that are available unequivocally contradict the notion that exposure from the Products could be “significant” in the causal sense, even crediting the miniscule amounts of asbestos that Drs. Longo and Rigler claim to have found. This is all the more so in light of the fact that Drs. Longo and Rigler made no effort to calculate the “dose” of talc individuals are likely to use. As defense expert Dr. Nadia Moore explains, Drs. Longo and Rigler’s approach of simply assuming that the alleged presence of asbestos in a sample of the Products means users of the Products were exposed to “significant” amounts of asbestos in the air is “like measuring the amount of vodka in a bottle and concluding that an individual would more likely than not have gotten drunk or had a high risk of

²²³ (2d Suppl. Longo Rep. at 32.)

²²⁴ (Longo 4/17/19 *Weirick* Dep. 147:25-148:3.)

getting drunk, without considering how much vodka an individual actually consumed.”²²⁵ In essence, Drs. Longo and Rigler’s “significant exposure” opinion is simply an unscientific “any exposure” opinion dressed up in different verbiage, and it is just as unreliable.

For this reason, too, plaintiffs’ experts’ opinions that asbestos in talc can cause ovarian cancer must be excluded as unreliable.

IV. PLAINTIFFS LACK RELIABLE SCIENTIFIC EVIDENCE THAT ASBESTOS WAS PRESENT IN THE TALC ORE USED TO SOURCE THE PRODUCTS.

Finally, in an effort to boost their flawed arguments that the Products contain asbestos, plaintiffs have proffered Drs. Cook and Krekeler to opine that the mines that defendants used to source talc contained asbestos and that, as a result, the Products do too.²²⁶ In addition, Dr. Krekeler (though not a medical professional of any kind) has opined that nonasbestiform cleavage fragments are similar to asbestos and pose the same risks to human health.²²⁷ As explained below, these opinions – on which no other experts rely – are unreliable because they are based on a review of historical testing documents and literature largely handpicked by plaintiffs’ counsel and not tied sufficiently to the products at issue in this litigation.

²²⁵ (Moore Rep. at 44.)

²²⁶ (Am. Cook Rep. at 9-21, 42; Krekeler Rep. at 1, 14-23.)

²²⁷ (Krekeler Rep. at 3-4.)

A. Plaintiffs’ Experts’ Opinions Regarding The Alleged Presence Of Asbestos In Talc Ore Used To Source The Products At Issue Are Not Supported By The Data On Which They Rely.

The Court should exclude Drs. Cook and Krekeler’s opinions about the alleged presence of asbestos in talc because their opinions are not derived from reliable methods and are not supported by the data on which they rely.

1. Drs. Cook And Krekeler unreliably base their opinions on counsel-generated collections and summaries of documents.

Drs. Cook and Krekeler’s opinions are unreliable and inadmissible because the underlying data were not assembled or analyzed pursuant to any recognized methodology. Instead, they support their opinions with identical charts in their reports – assembled by plaintiffs’ counsel – that identified documents that counsel deemed relevant and included counsel’s interpretation of the same documents. This is not a reliable method.

An expert may not be used as a mere vessel through which to funnel “information provided to her by a party.” *State Farm Fire & Cas. Co. v. Electrolux Home Prods., Inc.*, 980 F. Supp. 2d 1031, 1048 (N.D. Ind. 2013); *see also King-Indiana Forge, Inc. v. Millennium Forge, Inc.*, No. 1:07-CV-00341-SEB-DM, 2009 WL 3187685, at *2 (S.D. Ind. Sept. 29, 2009). In particular, an expert cannot rely on a summary of the record evidence prepared by a party’s counsel. *See Crowley v. Chait*, 322 F. Supp. 2d 530, 546 (D.N.J. 2004) (citing *In*

re TMI Litig., 193 F.3d 613, 697-98 (3d Cir. 1999), *amended in nonmaterial part*, 199 F.3d 158 (3d Cir. 2000)). But that is exactly what happened here.

Pages 13-20 of Dr. Cook's report contain a lengthy chart of company documents that is *virtually identical* to another chart of the same documents on pages 14-23 of Dr. Krekeler's report. The charts contain not only the same documents, organized in the same fashion, but also (identical) substantive remarks about each document, either in the form of a quotation or a brief summary of its relevant contents.²²⁸ This is no cosmic coincidence, but rather reflects the same underlying work by plaintiffs' counsel. As Dr. Krekeler explained at his deposition, he "asked [plaintiffs'] counsel to create the chart[]." ²²⁹ Thus, critically, the analyses of the documents reflected in these charts plainly were not the work of Drs. Cook and Krekeler but of counsel.

That is not a scientific method. Experts are supposed to form their own opinions of the evidence – not merely serve as a pass-through for the conclusions

²²⁸ Drs. Cook and Krekeler also include identical tables of purported fibrous talc samples and appear to acknowledge that those tables were also made by counsel. (*See, e.g.*, Cook Dep. 56:8-19 (noting counsel helped with the tables).)

²²⁹ (Dep. of Mark Krekeler, Ph.D. ("Krekeler Dep.") 39:9-13, Jan. 25, 2019 (attached as Ex. B34 to Tersigni Cert.)) Dr. Cook similarly acknowledged that the tables were compiled by plaintiffs' counsel and sent to him to include in his report. (Cook Dep. 60:21-61:8.) When Dr. Cook was asked whether he had reviewed all of the documents in the tables, he responded, "I think I have." (*Id.* 60:6-8.)

of the counsel who are paying them.²³⁰ For this reason alone, the Court should exclude these experts' opinions as unreliable.

2. The counsel-selected documents on which Drs. Cook and Krekeler rely in any event fail to furnish a reliable basis for their conclusions.

Drs. Cook and Krekeler's opinions are also unreliable and inadmissible because the documents on which they rely do not support their conclusions.

Expert testimony must be excluded when there is too great an analytical gap between the expert's opinion and the data on which the expert relies. *See Joiner*, 522 U.S. at 146; *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 159 (3d Cir. 1999) (expert's testimony was properly excluded because it "did not reliably flow from [the] data and methodology"). Relatedly, it is well settled that an expert opinion is inadmissible when the only connection between the conclusion and the existing data is the expert's own assertions. *See In re TMI Litig.*, 193 F.3d at 668, 670 (citation omitted) (an expert's opinion is subject to attack when he "relies in part on his own *ipse dixit*, rather than on something more readily verifiable"); *see also Hughes v. Kia Motors Corp.*, 766 F.3d 1317, 1331 (11th Cir. 2014) (upholding exclusion of a proposed expert opinion; the expert's "leap from data to opinion was too great").

²³⁰ As the next sections illustrate, the consequence of Drs. Cook and Krekeler's complete deference to plaintiffs' counsel's analysis of the documents is that their opinions are not supported by those documents.

Consistent with these principles, courts exclude expert opinions as unreliable when the expert's opinions are not supported by the data on which they rely. *See, e.g., Bowers v. Nat'l Collegiate Athletic Ass'n*, 564 F. Supp. 2d 322, 353-54 (D.N.J. 2008) (expert testimony unreliable where "data upon which [expert] supposedly relied . . . [did] not support the opinion [the expert] drew from the data"); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007) (report did not support expert's methodology because it focused exclusively on the reporting rate of rhabdomyolysis despite the fact "that reporting rates are a crude measure of reports received by the FDA" affected by many factors); *Finestone*, 2006 WL 267330, at *12 (excluding expert testimony that sewage sludge dumped at a waste site contained radioactive isotopes because the experts' extrapolations as to the presence and type of the radioactive isotope "[could] not stand next to the actual data retrieved from the site and surrounding environment"); *Anderson v. Bristol Myers Squibb Co.*, No. CIV.A. H-95-0003, 1998 WL 35178199, at *11 (S.D. Tex. Apr. 20, 1998) (expert's opinion that staph infection caused plaintiff's disease was unreliable where the studies on which she relied as support for the conclusion that staph infections *could* cause that disease "never even reached" that conclusion themselves).

Here, Drs. Cook and Krekeler's opinions regarding the presence of asbestos in the talc ore used to source the Products are not in any way tethered to the actual

data on which they are based because: (1) their opinions are premised on testing and reports regarding mines from which defendants did not source talc for the Products; (2) they rely on reports and testing of non-ore mineral specimens; and (3) none of the testing documents on which they rely actually identified any asbestiform minerals.

a) Drs. Cook and Krekeler rely on data from mines that were not used to source cosmetic talc.

First, Drs. Cook and Krekeler rely on documents that have nothing to do with the issues presented in this litigation because they are from geographic regions and mines that were *not* sources of talc for the Products. For example:

- Dr. Krekeler relies on historical testing reports from mines in China that he acknowledged were not used by defendants to source cosmetic talc.²³¹
- Dr. Cook cites studies and literature about regional geology that are not specific to the mines used for defendants' cosmetic talc products.²³²
- Dr. Cook opines that there was "significant" potential for asbestos to be present in the Products because "[p]otentially asbestiform amphiboles . . .

²³¹ (See, e.g., Krekeler Dep. 195:22-25 (conceding that he has no evidence that talc from the Maanshan deposit was used in defendants' cosmetic talc); Krekeler Rep. at 11 (stating that the Shandong Province of China was associated with amphiboles—although that area is thousands of kilometers from any mine defendants used to source talc for the Products).)

²³² (See Am. Cook Rep. at 10 (citing letter indicating chrysotile was found in the Val Chisone region generally, not the Fontane mine where defendants sourced talc for the Products); Cook Dep. 248:9-17 (acknowledging that the studies he cites do not identify chrysotile in the Fontane mine); Cook Dep. 251:7-10 (same).) Note that studies examining the Italian mine where defendants actually sourced their talc did not detect any asbestiform minerals. (See Poulton Rep. at 8.)

are reported from a variety of Vermont talc-related serpentinite localities,” including the Carlton Mine, the Hammondsville mine, the Barton stateite quarry, the Holden talc quarry, Rochester verde antique quarry and the Mad River mine.²³³ But with the exception of Hammondsville, none of these locations was actually used as a source of cosmetic-grade talc used in the Products.²³⁴ And with respect to Hammondsville, the studies on which Dr. Cook relies did not identify any asbestiform materials.²³⁵

- Drs. Cook and Krekeler rely on several samples in which the McCrone laboratory detected chrysotile asbestos in 1985 and 1986.²³⁶ But the samples came from the Red Hill mine in San Andreas, California, a mine from which cosmetic talc was never sourced for the Products,²³⁷ and one that is *thousands of miles away* from the Vermont, Italian and Chinese talc that is almost exclusively at issue here.
- Drs. Cook and Krekeler rely on testing by The Colorado School of Mines Research Institute on split core samples from a Vermont exploration program in February 1973.²³⁸ The samples came from north of the Frostbite mine, which never produced talc that went into the Products.²³⁹
- Drs. Cook and Krekeler rely on the testing and characterization of a sample named FD-14 to suggest that cosmetic talc sourced for the Products was contaminated with tremolite asbestos.²⁴⁰ But Sample FD-14 came from the Gouverneur mine in New York, which was never used

²³³ (See Am. Cook Rep. at 11.)

²³⁴ (See Poulton Rep. at 8 (citing JNJTALC000168988; JNJ 000404692; JNJ000314938; JNJTALC000239225).)

²³⁵ (Poulton Rep. at 8.)

²³⁶ (See, e.g., Am. Cook Rep. at 18; Krekeler Rep. at 21.)

²³⁷ (See Poulton Rep. at 9 (citing JNJ 000065646; JNJ 000578888; IMERYS 013723).)

²³⁸ (See, e.g., Am. Cook Rep. at 15; Krekeler Rep. at 17.)

²³⁹ (Poulton Rep. at 9.)

²⁴⁰ (See, e.g., Am. Cook Rep. at 23; Krekeler Rep. at 25.)

to source cosmetic talc for the Products.²⁴¹

In addition, many of the data on which Drs. Cook and Krekeler rely were derived from testing in mines that were used to produce *industrial talc* – not cosmetic-grade talc. For instance, Drs. Cook and Krekeler rely on a test result for sample D-GI from the McCrone Laboratory, indicating that the sample contained chrysotile asbestos.²⁴² But that sample is from Gassetts Mill, which produced industrial talc that was never used in the Products.²⁴³

Data on regions and mines where defendants did not even source talc for the Products cannot support Drs. Cook and Krekeler’s conclusions that the deposits from which defendants *did* source their talc contained asbestos. This is especially true considering that even plaintiffs’ experts have admitted that each talc deposit is unique and must be evaluated individually to determine which minerals are present.²⁴⁴ Their opinions must be excluded as unsupported and unreliable. *See Bowers*, 564 F. Supp. 2d at 354.

²⁴¹ (Poulton Rep. at 9-10.)

²⁴² (*See, e.g.*, Am. Cook Rep. at 25; Krekeler Rep. at 26.)

²⁴³ (*See* Poulton Rep. at 10 (citing JNJMX68_000002659).)

²⁴⁴ (*See* Cook Dep. 166:8-23 (agreeing that one would need to “look at the individual deposit” to determine its composition); *see also* Expert Report of Ann G. Wylie, Ph.D. (“Wylie Rep.”) at 18-19, Feb. 25, 2019 (attached as Ex. C6 to Tersigni Cert.) (explaining that “every deposit is unique in some way(s)”).)

b) *Drs. Cook and Krekeler improperly rely on testing of non-ore mineral specimens.*

Drs. Cook and Krekeler also improperly rely on papers and reports that involved testing of **non-ore** mineral specimens from the mines – not the talc used for the Products. For example, Dr. Cook concludes that testing of Italian talc identified both tremolite and actinolite.²⁴⁵ But the same document on which he relies to support that conclusion makes clear that the samples tested “**do not represent an average collection of specimens of material being produced at the mine. The specimens were collected with the intention of sampling those areas with obvious non-talc mineral inclusions.**”²⁴⁶ In other words, the tests were specifically conducted with the intention of identifying impurities in the non-ore material within the mines. As defendants’ expert Dr. Poulton explained, “[t]hese tests were conducted not to characterize the ore that was being processed and used in products, but to describe the impurities that **were not** in ore material. . . . Such a study of non-ore areas within the mine indicates that the surrounding waste rock was mapped in a responsible manner.”²⁴⁷ Moreover, as Dr. Cook fails to mention,

²⁴⁵ (Am. Cook Rep. at 10 (citing JNJ_000030983; JNJ 000016791; JNJ 000060592; JNJ 000238194; and JNJ 000322351).)

²⁴⁶ (See JNJ000322351-475 at 354 (attached as Ex. D2 to Tersigni Cert.).)

²⁴⁷ (See Poulton Rep. at 6 (emphasis added).) Similarly, Drs. Cook and Krekeler cite a report on Italian talc done by Dr. Fred Pooley of University College in Cardiff, Wales supposedly identifying fibrous tremolite and actinolite. (Am. Cook Rep. at 10; Krekeler Rep. at 10.) But these samples did not come from the

the same study also concluded that when talc specimens were taken from the mines, *no tremolite was detected in those specimens*.²⁴⁸ In other words, once again, these tests do not say anything about the presence of asbestos in any talc that actually would have been used in the Products. Nor do plaintiffs' experts explain how this irrelevant data could support their conclusions regarding asbestos contamination in the Products. For this reason too, "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146.

c) *Drs. Cook and Krekeler fail to differentiate between asbestiform and non-asbestiform minerals.*

Both Drs. Cook and Krekeler concede that amphiboles, such as tremolite, are not always asbestos; rather, they must form in the rare asbestiform habit to be asbestos.²⁴⁹ However, both Drs. Cook and Krekeler ignored this distinction in reaching their opinions. For example, Drs. Cook and Krekeler each cite reports from the Battelle Memorial Institute, an organization that tested cosmetic talc samples in the 1950s, for the proposition that cosmetic talc contained tremolite.²⁵⁰ But as Dr. Krekeler conceded at his deposition, the Battelle report does not indicate

talc ore. (Poulton Rep. at 6.)

²⁴⁸ (See *id.*)

²⁴⁹ (See Krekeler Dep. 166:17-167:3 (acknowledging that tremolite may occur in an asbestiform or non-asbestiform habit); Cook Dep. 108:14-20 (agreeing that asbestos is defined as the asbestiform version of amphiboles).)

²⁵⁰ (See Am. Cook Rep. at 10; Krekeler Rep. at 9.)

that the tremolite identified was of the asbestiform variety.²⁵¹ The presence of non-asbestiform minerals in the mines where defendants sourced their talc cannot support Drs. Cook and Krekeler's logical leap to the conclusion that those mines also contained the asbestiform variety of those minerals, and as explained in connection with Drs. Longo and Rigler's opinions, their failure to account for the distinction in mineral habits renders their entire analysis unreliable and inadmissible.²⁵²

In sum, plaintiffs' experts' opinions regarding the alleged presence of asbestos in the talc ore used to source the Products are unsupported by the data on which they are supposedly based. Because there is too great an analytical gap between their opinions and the data, their opinions must be excluded.²⁵³

²⁵¹ (Krekeler Dep. 166:17-19.)

²⁵² Drs. Cook and Krekeler's unreliable conflation is no accident. As defendants' expert, Laura Webb, Ph.D., explains, "[t]here is no well-founded, scientifically-sound evidence in the peer-reviewed scientific literature for an association of amphibole asbestos with the talc deposits of concern." (Expert Report of Laura Webb, Ph.D. at 1, Feb. 25, 2019 (attached as Ex. C29 to Tersigni Cert.); *see also id.* at 24.)

²⁵³ Drs. Cook and Krekeler's opinions that mining and talc ore sampling techniques used in manufacturing the Products were not adequate to remove asbestos from talc (*see, e.g.*, Am. Cook Rep. at 2-3; Krekeler Rep. at 1-2) should also be excluded because they are irrelevant. *See, e.g., El Aguila Food Prods., Inc. v. Gruma Corp.*, 131 F. App'x 450, 453-54 (5th Cir. 2005) ("[A]bstract conclusions not adequately grounded in the facts of the case" or "anchored to the specific" conduct at issue are inadmissible). Even assuming that these opinions were scientifically reliable – which they are not – they would not have any bearing on any claim or fact at issue in this litigation, because, as explained below,

B. Dr. Krekeler Lacks A Reliable Basis For His Opinions That Cleavage Fragments Are “Asbestiform Particles” That Have The Same Health Risks As Asbestos.

Dr. Krekeler also asserts that “nonasbestiform minerals such as large crystals of tremolite or anthophyllite could be modified during processing and be turned into asbestiform particles with the same health risks as asbestos.”²⁵⁴ As set forth in Defendants’ Memorandum in Support of Motion to Exclude Certain Plaintiffs’ Experts’ Opinions for Lack of Qualifications, Dr. Krekeler is not qualified to offer this opinion. But even if he were, this opinion – like his others – cannot survive even cursory scrutiny.

First, there is no scientific support for Dr. Krekeler’s claim that a non-asbestiform mineral can be “modified” to become asbestiform even if it did not form naturally in an asbestiform habit.²⁵⁵ As discussed above, plaintiffs’ primary

plaintiffs have not presented any reliable evidence of asbestos contamination in the Products.

²⁵⁴ (Krekeler Rep. at 3-4.) For example, according to Dr. Krekeler, “crushing or milling” nonasbestiform minerals can “result in producing asbestiform materials or fibers.” (Krekeler Dep. 76:21-77:4.)

²⁵⁵ (See Wylie Rep. at 10 (“Mineral fiber cannot be produced from cleavage fragments. I am unaware of any literature that supports the notion that non-asbestiform minerals such as tremolite could be modified during processing and turned into asbestos. If a mineral does not form as fibers in nature, it cannot form the very thin fibers characteristic of asbestos by crushing it.”).)

expert on this topic, Dr. Longo, has acknowledged that crushing up nonasbestiform rock does not magically transform it into an asbestiform mineral.²⁵⁶

When pressed on this opinion at his deposition, Dr. Krekeler could not point to a single scientific article, report from a regulatory agency, or any other published authority suggesting that such a modification was possible.²⁵⁷ Instead, he explained that his opinion was primarily based on his “knowledge of crystal chemistry” and what he was “taught” during his undergraduate and graduate studies.²⁵⁸ Dr. Krekeler also acknowledged that he had never “presented or published” this opinion for the broader scientific community.²⁵⁹

In fact, the relevant science confirms that, while “cleavage fragments have the same chemical composition as the corresponding asbestos fibres,” they *do not* have “all the dimensional characteristics (length, diameter and aspect ratio), chemical and physical properties, or mechanical performance of asbestiform

²⁵⁶ (Rimondi Trial Tr. Vol. I 147:23-148:2.)

²⁵⁷ (Krekeler Dep. 77:9-78:11.)

²⁵⁸ (*Id.*; see also *id.* 78:24-79:2 (“I think, based on my experience and what I know about crystal chemistry of minerals, that is a reasonable interpretation.”); *id.* 105:1-5 (confirming that his definition of the difference between asbestiform fiber and cleavage fragment comes from his “undergraduate and graduate” coursework and “general” discussions with individuals in the industry about minerals other than talc).)

²⁵⁹ (*Id.* 78:24-79:2.)

fibres.”²⁶⁰ Likewise, a report published by the U.S. Department of Interior Bureau of Mines – which Dr. Krekeler concedes is a “generally” reliable source – makes clear that, because cleavage fragments “did not grow as fibers, they cannot have the characteristics of fibers.”²⁶¹ Because the literature (and plaintiffs’ own expert Dr. Longo) contradicts Dr. Krekeler’s unsubstantiated *ipse dixit*, it must be excluded. *See, e.g., Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 406 (3d Cir. 2003) (in the absence of literature, an expert opinion must have other indicia of reliability); *In re TMI Litig.*, 193 F.3d at 668, 670 (an expert’s opinion is subject to attack when he “relies . . . on his own *ipse dixit*, rather than on something more readily verifiable”).

Second, Dr. Krekeler’s suggestion that exposure to cleavage fragments poses “the same health risks as asbestos” is also outside his area of expertise, not to mention unsupported by reliable science. Because he is not a medical doctor or an epidemiologist, Dr. Krekeler does not purport to have any independent opinion as to whether exposure to asbestos – or cleavage fragments that have purportedly

²⁶⁰ *See* Robert-Sauve Research Institute in Occupational Health and Safety (“IRRST”), Studies and Research Projects: Synthesis of Knowledge on Tremolite in Talc (Report R-755) at 10 (2012) (“IRRST 2012”) (attached as Ex. A122 to Tersigni Cert.) (cited in Krekeler Rep. at 4 n.5); *see also* IARC 2010 Monograph at 277 (differentiating between asbestos and cleavage fragments and explaining that, when minerals occur in an asbestiform habit, “they constitute asbestos and, when not asbestiform, they are referred to as mineral fragments or cleavage fragments”).

²⁶¹ Campbell 1977 at 30.

been “modified” to asbestos – causes any disease.²⁶² Instead, in opining that exposure to cleavage fragments can have “dangerous health effects,” Dr. Krekeler relies solely on “documents and things [he’s] read”²⁶³ – specifically, two reports published by NIOSH and IRRST.²⁶⁴ Neither of these reports supports the notion that nonasbestiform cleavage fragments have the same health risks as asbestos.²⁶⁵ NIOSH concluded that, while “[a]sbestos fibers are clearly of substantial health concern,” “[f]urther research is needed to better understand health risks associated with exposure to other thoracic-sized [elongated mineral particles], including those with mineralogical compositions identical or similar to asbestos minerals[.]”²⁶⁶

²⁶² (Krekeler Dep. 114:13-16.)

²⁶³ (*Id.* 114:17-20.)

²⁶⁴ (Krekeler Rep. at 4.)

²⁶⁵ This is unsurprising, as Dr. Krekeler has no expertise in this field. (*See* Defendants’ Memorandum in Support of Motion to Exclude Certain Plaintiffs’ Experts’ Opinions for Lack of Qualifications at 13-15.) “[A] court should ‘exclude proffered expert testimony if the subject of the testimony lies outside the witness’s area of expertise.’” *In re Diet Drugs*, 2001 WL 454586, at *7 (quoting 4 Weinstein’s Fed. Evid. § 702.06[1], at 702-52 (2000)). Further, “[a] scientist, however well credentialed he may be, is not permitted to be the mouthpiece of . . . a different specialty.” *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002).

²⁶⁶ NIOSH 2011 at v. Although NIOSH has promulgated a Recommended Exposure Limit (“REL”) for asbestos that encompasses cleavage fragments that are similar in dimension to asbestos fibers, NIOSH has expressly agreed that the science “do[es] not provide clear answers regarding the toxicity” of non-asbestiform fibers and has decided to regulate such fibers pursuant to a “precautionary approach” that seeks to avoid the difficulties of “distinguish[ing] between asbestos fibers and nonasbestiform” fibers. *Id.* at 19, 29.

IRRSST came to the same determination, stating that “a conclusion cannot be reached about the biological effects from the distinction between cleavage fragments and asbestos fibres.”²⁶⁷

Other than those two reports, Dr. Krekeler was not able to point to a single study supporting his opinion that cleavage fragments pose the same health risks as asbestiform fibers.²⁶⁸ Again, this is no surprise given that multiple studies have shown that “there is *no convincing evidence* for the pathogenicity of cleavage fragments.”²⁶⁹ Indeed, as Dr. Wylie explains, “while asbestos fiber bundles may

²⁶⁷ IRRST 2012 at 37. When confronted with the conclusions of both of these organizations, Dr. Krekeler conceded that each report “says what it says.” (Krekeler Dep. 117:25-118:25.) And he was unable to point to any studies actually supporting his opinion. (*Id.* 119:6-11.)

²⁶⁸ (Krekeler Dep. 119:6-11.)

²⁶⁹ Roggli & Green, *Dimensions of Elongated Mineral Particles: A Study of More Than 570 Fibers From More Than 90 Cases with Implications for Pathogenicity and Classification as Asbestiform vs. Cleavage Fragments*, Ultrastruct Pathol. 1-2 (2019) (attached as Ex. A123 to Tersigni Cert.) (emphasis added); see also, e.g., Gamble & Gibbs, *An Evaluation of the Risks of Lung Cancer and Mesothelioma from Exposure to Amphibole Cleavage Fragments*, 52 Regul Toxicol Pharmacol. S154, S179 (2008) (attached as Ex. A40 to Tersigni Cert.) (concluding that “the experimental data . . . provide strong support for the epidemiological findings that the risks of lung cancer and mesothelioma are considerably less [or absent] for persons exposed to amphibole cleavage fragments when compared to persons exposed to amphibole asbestos fibers”); Addison & McConnell, *A Review of Carcinogenicity Studies of Asbestos and Non-Asbestos Tremolite and Other Amphiboles*, 52 Regul Toxicol Pharmacol. S180, S197 (2008) (attached as Ex. A3 to Tersigni Cert.) (concluding that “fibers in excess of 20 µm and with diameters less than 1 µm are necessary to cause cancer,” which explains “the lack of carcinogenicity of cleavage fragment fibers of amphiboles since these

disaggregate after entering the respiratory system, resulting in increases in the dose of fiber over time, cleavage fragments do not disaggregate after entering the body because they are single structures.”²⁷⁰

Moreover, Dr. Krekeler’s opinions that cleavage fragments can be “modified” to create asbestiform particles, which pose the “same health risk as asbestos,” are based on nothing more than his *ipse dixit* and should therefore be excluded as unreliable.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court exclude plaintiffs’ experts’ opinions regarding the alleged presence of asbestos in defendants’ talcum powder.

rarely if ever contain fibers of these critical dimensions”). (See also Mossman Rep. at 20-22 (explaining that “animal studies demonstrate no cancers after exposures to cleavage fragments” and that “*in vitro* studies demonstrate that cleavage fragments do not induce oxidant production and markers of inflammation and cancer development”).)

²⁷⁰ (Wylie Rep. at 10.)

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Respectfully submitted,

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